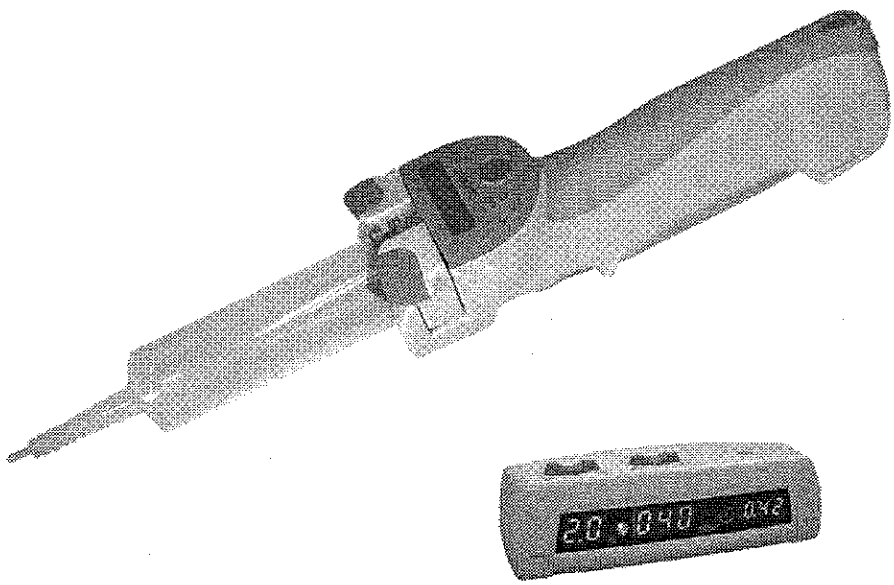
MALLINCKRODT

LIEBEL-FLARSHEIM

OptiStat™

Contrast Delivery System



Operators, Service and Installation

810600-B

MALLINCKRODT

FOREWORD

Congratulations on the purchase of your Liebel-Flarsheim OptiStat™ Injection System. The OptiStat represents our effort to provide a quality product to support better health care throughout the world.

Regardless of how well equipment is designed, misuse or abuse will deny its owner the expected quality of service. Misuse or abuse may occur unintentionally because the proper method of operating the equipment is unknown. Read this manual carefully before operating the OptiStat. Retain this manual for future reference.

LIEBEL-FLARSHEIM TECHNICAL SUPPORT
Phone No. 1-800-877-0791

RECORDING SERIAL NUMBERS AND SOFTWARE VERSIONS

To facilitate requests for information, replacement parts or optional accessories, please record the serial numbers (S/N) located on the components along with the listed data.

Powerhead S/N ☐☐☐☐☐☐☐☐

Console S/N ☐☐☐☐☐☐☐☐

Power Supply S/N ☐☐☐☐☐☐☐☐

Date of Installation ☐☐/☐☐/☐☐

Installing Company _____

Address _____

Phone Number _____

OptiStat™ is a trademark of Mallinckrodt, Inc.

MEANINGS OF SYMBOLS USED IN THIS MANUAL

Please regard any message that follows the word Danger, Warning or Caution!

⚠ DANGER! ⚠

Hazards which could result in severe personal injury or death.

⚠ WARNING! ⚠

Hazards which could result in personal injury.

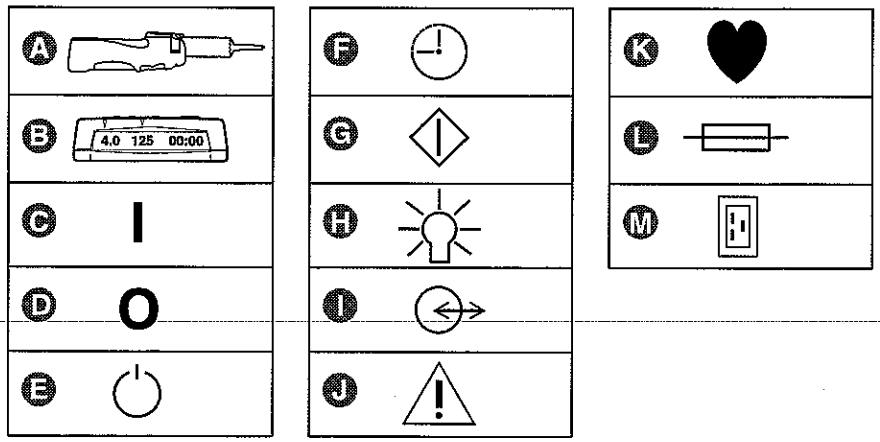
⚠ CAUTION! ⚠

Hazards which could result in equipment or property damage.

WARNING! — *Electrical hazards which could result in personal injury.*

Non-Anesthetic proof

MEANINGS OF SYMBOLS USED ON THE INJECTOR



Ⓐ Powerhead Connection—Indicates connection to the powerhead.

Ⓑ Console Connection—Indicates connection to the console.

Ⓒ Power On—Indicates main AC power is ON.

Ⓓ Power Off—Indicates main AC power is OFF.

Ⓔ Stand By—Turns ON and OFF power to the Console and Powerhead. The power supply remains on.

Ⓕ Elapsed Time Display—Timer counts up to 19:59 from the start of the injection.

Ⓖ Start—Starts the pre-programmed injection when necessary conditions are met.

Ⓗ Illumination—Indicator is illuminated when appropriate conditions are met.

Ⓘ Interface Connection —Indicates connection to CAN Interface

Ⓙ Refer to Manual—Reference the manual for more information.

Ⓚ Medical Device—Indicated Medical Equipment.

Ⓛ Fuse—Indicates location of main fuse. Also includes value of fuse.

Ⓜ Power Input—Indicates location of main AC power input.

CLASSIFICATION IN ACCORDANCE WITH I.E.C. 601

Type of protection against electric shock

Class I equipment

Degree of protection against electric shock

Type CF applied part (Powerhead).

Degree of Protection against ingress of water

Ordinary Equipment.

UL Information

OptiStat
CLASSIFIED BY UNDERWRITERS LABORATORIES INC.
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 2601-1
33SL

OptiStat
CLASSIFIED WITH RESPECT TO ELECTRIC SHOCK, FIRE MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2 NO. 601.1,
33SL

CE Mark

CE 0123

Authorized EC Representative
TYCO HEALTHCARE UK LTD
154 FAREHAM ROAD
GOSPORT PO13 OAS UK

ELECTROMAGNETIC COMPATIBILITY

The OptiStat meets the radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices

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1 OPERATOR'S MANUAL

1.1 OVERVIEW OF MANUAL

The purpose of this section of the manual is to provide instructions for using the Liebel-Flarsheim OptiStat in order to ensure patient safety. For safe operation, it is important that this section of the manual be read carefully and its recommended procedures followed.

1.1.1 INDICATIONS FOR USE

The OptiStat Injector is designed to inject a radiopaque contrast medium into a patient's vascular system which enhances diagnostic images obtained with X-ray procedures. Each injection is accomplished with a motor-driven syringe mechanism with microprocessor control of the flow rate, volume, and timing.

This manual provides operating procedures for the OptiStat Injectors which includes an overview of the injector, specifications, descriptions of system components, operating instructions, system generated messages, care of equipment and troubleshooting.

Contraindications for the use of this device are determined by the prescribing physician at the time of use and upon the contrast media package inserts.

1.1.2 USER QUALIFICATIONS

The OptiStat should ONLY be operated by qualified health care professionals who are:

- completely familiar with the unit,
- have read and understand this Operator's Manual, and
- are otherwise trained in the use of equipment and procedures of this type.

⚠ CAUTION! ⚠

Federal (USA) law restricts this device to sale by or on the order of a physician. (21CFR 801.109(6)(1))

1.1.3 SYSTEM CONFIGURATION

The OptiStat Contrast Delivery System is specially designed to be used in conjunction with X-ray equipment. The unit consists of the following components as shown in Figure 1-1-1.

Ⓟ Powerhead: contains all of the controls and interfaces necessary for contrast delivery.

- ⓐ Powerhead Coiled Cord (10': 3.048M)
- ⓑ Wall Plate
- ⓒ Powerhead Extension Cable (75': 22.86M)
- ⓓ Ultraject Pre-filled Syringe or 130 L-F Empty Syringe
- ⓔ Wall Hanger Assembly

Ⓢ Power Supply: provides the main power as well as the connection hub for the Powerhead Cable, Console Cable and optional Interface Cable.

- ⓕ Line Cord (10': 3.048M)
- ⓖ Interface Connector

Ⓒ Remote Control Console: duplicates the Powerhead keypad controls and additionally includes a timer that starts when the injection is initiated. The OptiStat can be programmed and operated from a remote location by the inclusion of the *optional* Remote Control Console.

- ⓗ Console Cable (7': 2.13M)

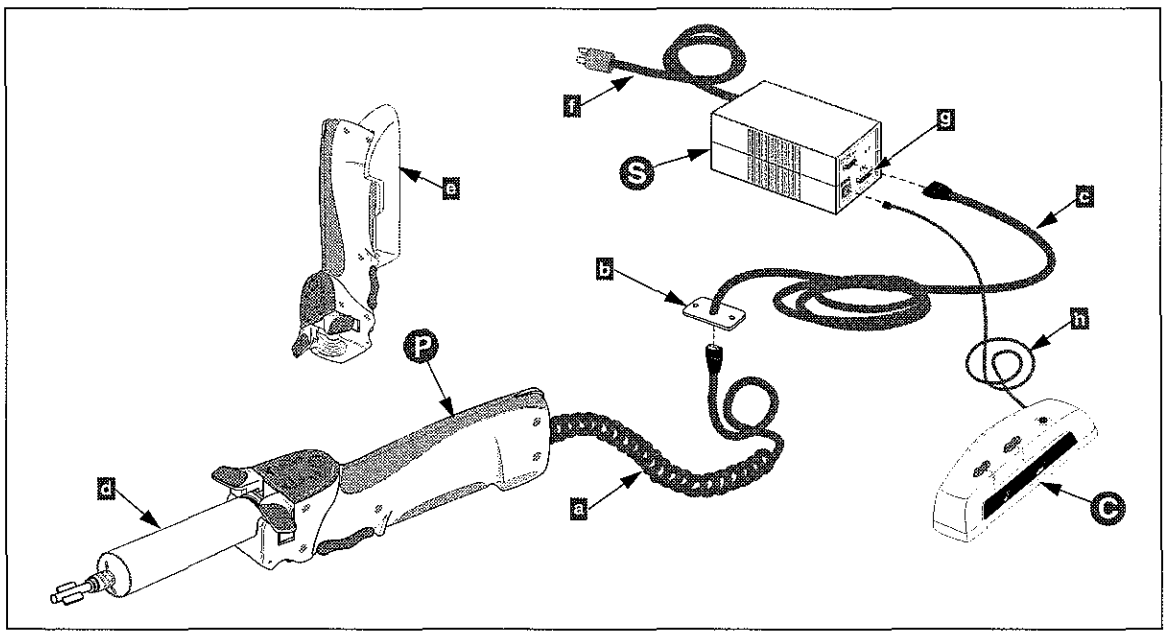


Figure 1-1-1 System Configuration

1.1.4 SYSTEM FEATURES

Versatility

The injector is microprocessor-controlled and can perform injections with the following variable parameters:

- Flow Rate
- Volume
- Pressure Limit

Interaction

The operator interacts with the system by using the controls on the powerhead and/or on the console.

1.1.5 SPECIAL FEATURES

The OptiStat has been designed to ensure the safety of both patient and operator. Specific safety features of the injector include:

Power -Up Self Test

When the OptiStat unit is switched "ON," it automatically performs a series of power-up tests to monitor the status of all injector systems. If the microprocessor detects any errors during power-up, an appropriate error code will appear in the system display. Also, during injection, all critical injector functions are constantly checked. If a fault is detected, the system will automatically shut down and the appropriate error code will appear in the system display.

Refer to *Chapter 2* for error code messages.

Electrically Isolated Syringe

All syringes are isolated from any electrical contact with the injector.

Enable Sequence to Minimize Air Embolism

In order to "enable" the OptiStat for an automatic injection, a specific sequence for loading the syringe and purging the air must be followed *(See section 1.5 Enabling the Injector for details)*. The enable sequence can only be accomplished from the powerhead requiring the operator to be in close contact with the OptiStat and the syringe. The enable sequence in itself does not guarantee that air has been completely removed from the system. The operator is responsible to ensure the syringe and the OptiStat have been properly primed and setup.

⚠ DANGER! ⚠

DANGER! AIR EMBOLISM HAZARD!

Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiStat Contrast Delivery System does not have the capability to check for air in the syringe and tubing. The operator is responsible for removing all air from the system.

Syringe Size Set-up

Since the OptiStat can accept various fill volumes for the pre-filled syringe as well as an empty syringe, the syringe size can be input in order to help prevent over-volume programming errors. The pre-programmed volume will be retained even if power is cycled. See section *1.4 Setting Values* for details.

⚠ CAUTION! ⚠

Programming volumes of partial pre-fills for more than their labeled volume can cause equipment damage.

Automatic Pressure Limit

The pressure that the OptiStat develops to deliver the injection is based on the programmed flow rate.

Start/Stop Key on the Powerhead

Because the powerhead is near the patient during an injection, the [Start/Stop] key is integrated into the powerhead for quickly starting or stopping of an injection.

NOTE: Once an injection has been started, pressing any key on the powerhead or Console will pause the injection.

Remote Control Operation

An optional remote console is available for programming, starting or stopping the injection.

Positive Positioning of the Powerhead

The powerhead can be held by hand or hung on a mounting bracket that holds the powerhead in the desired position during injection.

1.1.6 SPECIFICATIONS

Dimensions

Control Console ..... 6.0 W x 2.0 D x 1.8 H inches

Powerhead ..... 2.55 W x 10.2 L x 3.0 H inches

Power Pack ..... 7.5 W x 4.0 D x 3.0 H inches

Weight

Control Console ..... 0.3 lbs

Powerhead ..... 2.0 lbs

Power Pack ..... 1.7 lbs

Power Requirements

Standby ..... less than 1 A

Standard ..... 100-120 VAC, 4 A, 50/60 Hz
230 VAC, 4 A, 50/60 Hz

Voltage Requirements

Unit automatically adapts for input voltages from 100 to 230 VAC.

Electrical Leakage

Chassis ..... less than 300 micro-amps.

Environmental

Storage Temperature ..... -4° to 140° F (-20° to 60° C)

Electromagnetic Compatibility (EMC): The Optistat Injector meets EN60601-1-2 for level B conducted and radiated emissions and EMI immunity.
NOTE: If any anomalies in the injector performance are noticed, identify devices within the immediate area that are capable of producing electromagnetic interference and call a qualified service representative.

⚠ DANGER! ⚠

Possible explosion hazard if used in the presence of flammable anesthetics. The unit is not designed for use in explosive environments.

⚠ WARNING! ⚠

The powerhead may only be operated in an area that is located beyond the 20 gauss limit. Operating the unit within magnetic fields that are higher than this limit may cause the unit to malfunction, resulting in operator or patient injury.

⚠ CAUTION! ⚠

The console and power supply are not spill-proof. Fluid spilled in these components can cause the unit to malfunction, resulting in patient or operator injury. If fluid is spilled on either component, remove from operation and contact your authorized service personnel.

⚠ DANGER! ⚠

Follow the manufactures guidelines and do not operate any part of the OptiStat system within 6 inches (15-cm) of a pacemaker and or defibrillator.

⚠ DANGER! ⚠

Blood clot hazard. Do not allow blood to remain in I.V. access line.

⚠ DANGER! ⚠

Contamination hazard. Do not reuse syringe or other I.V. access components.

Syringe Sizes

The OptiStat Injector uses the 125 ml style pre-filled syringe in the following fill volumes:

- 125 ml
- 100 ml
- 75 ml
- 50 ml

The OptiStat Injector uses the Liebel-Flarsheim 130 ml style empty syringe.

Catheters

Use only safety-approved catheters suitable for connection to the LLN-K-A Luer male-threaded locking coupler (DIN 13 090) of the Liebel-Flarsheim spiral extension tubing, Part Number 601195.

Programmable Flow Rate

0.1—6.0 ml/s in 0.1 increments

Retract after injection (or filling 130 ml) variable up to 7 ml/s

Programmable Volume

1—125 ml or preset pre-filled volume, or 130 ml in 1 ml increments.

Fill Rate

Variable up to 7 ml/sec.

Total Time

Total Time Display Parameters: 00:00—19:59 (minutes:seconds)

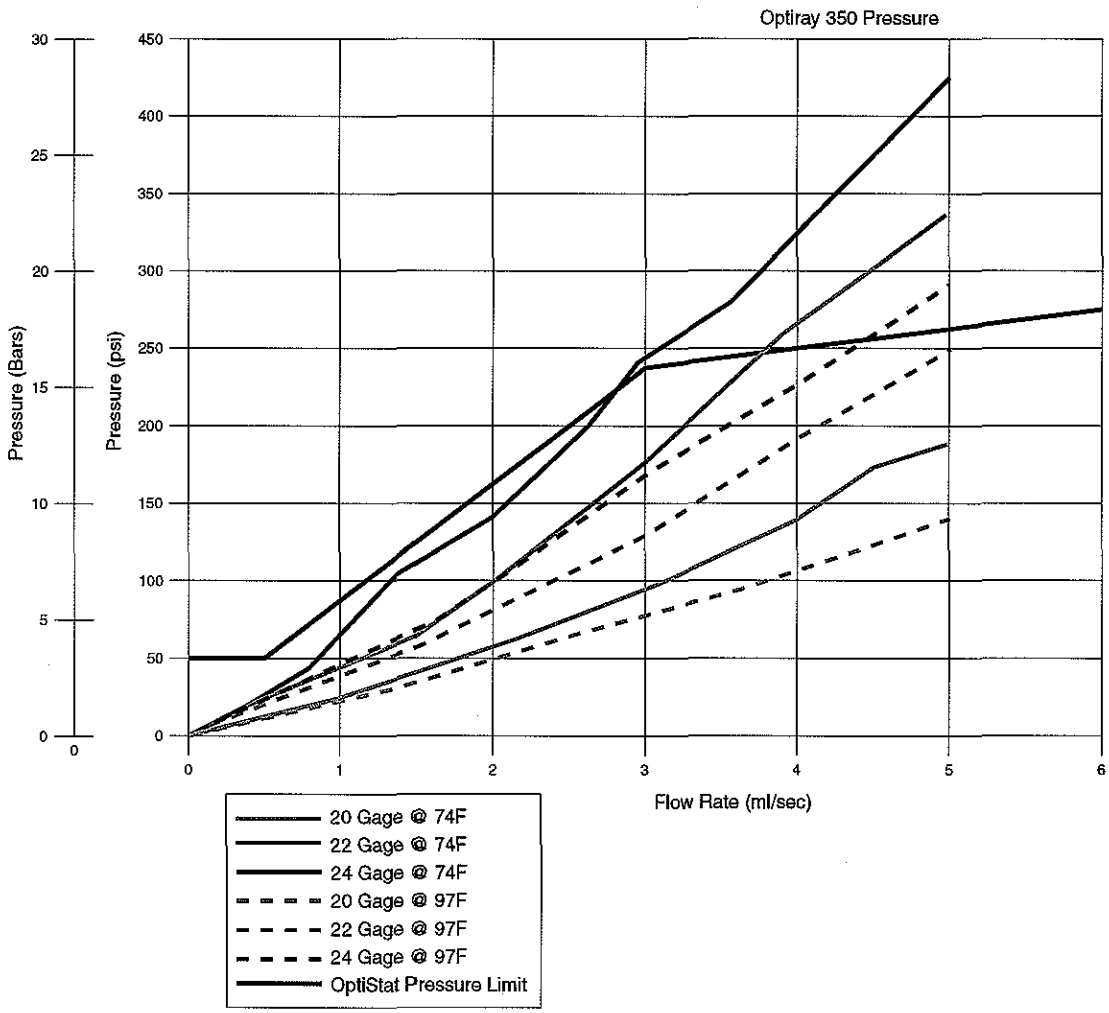
Automatic Pressure Limit

The pressure that the OptiStat develops to deliver the injection is limited based on the programmed flow rate. The table below defines the maximum allowable pressure for given flow rates.

The pressure limit is automatically set high enough to ensure that the desired flow rate is delivered under normal conditions. However, the flow rate will be limited if an obstruction is encountered. Also, combinations of high flow rate, viscous contrast, and small gage catheters may result in a pressure limit causing a reduced flow rate.

If the OptiStat senses an overpressure condition, it will alert the operator with an audible beep and reduce the flow rate to keep the pressure below the limit. If the flow rate drops below one half of the programmed limit for more than one second, the injection will automatically pause to allow the operator to fix the problem. Pressing the start button will restart the OptiStat.

The following graph indicates the typical pressure required for various injections. The OptiStat Pressure Limit line indicates the factory pre-set pressure limit.



1.1.7 CONSUMABLES

⚠ WARNING! ⚠

This device has been approved for use with only the consumables listed below. Use of other consumables could result in patient injury, operator injury, equipment damage, and/or injector performance issues (i.e. incorrect volume delivery, incorrect flow rate delivery, incorrect pressure, etc.). Safety certification of the consumables listed below has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

Syringes

Liebel-Flarsheim 130 ml

Mallinckrodt 125 ml prefilled style.

Low Pressure Tubing

- **P/N 801106** 60" Coiled Y-Tubing available from Mallinckrodt.
- **P/N 601195** 60" Coiled Tubing available from Mallinckrodt.

Catheters

Use only safety-approved catheters suitable for connection to the LLN-K-A Luer male-threaded locking coupler (DIN 13 090) of the Liebel-Flarsheim spiral extension tubing, Part Number 601195.

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1.2 SYSTEM POWER

1.2.1 TURNING THE SYSTEM POWER ON

Refer to Figure 1-2-1.

NOTE: The Injector should **not** be powered up with a syringe installed. An installed syringe during power up will be identified as a used syringe and not allow the injector to be enabled.

The main power switch [S1] is located on the rear of the Power Supply. To turn the unit "ON", the Power Supply Power switch must be toggled to the ON position. When the Power Supply power switch is turned "ON", the LED located in the upper right-hand corner of the Power Supply [S4] will glow and the display on the power head and the console will be illuminated.

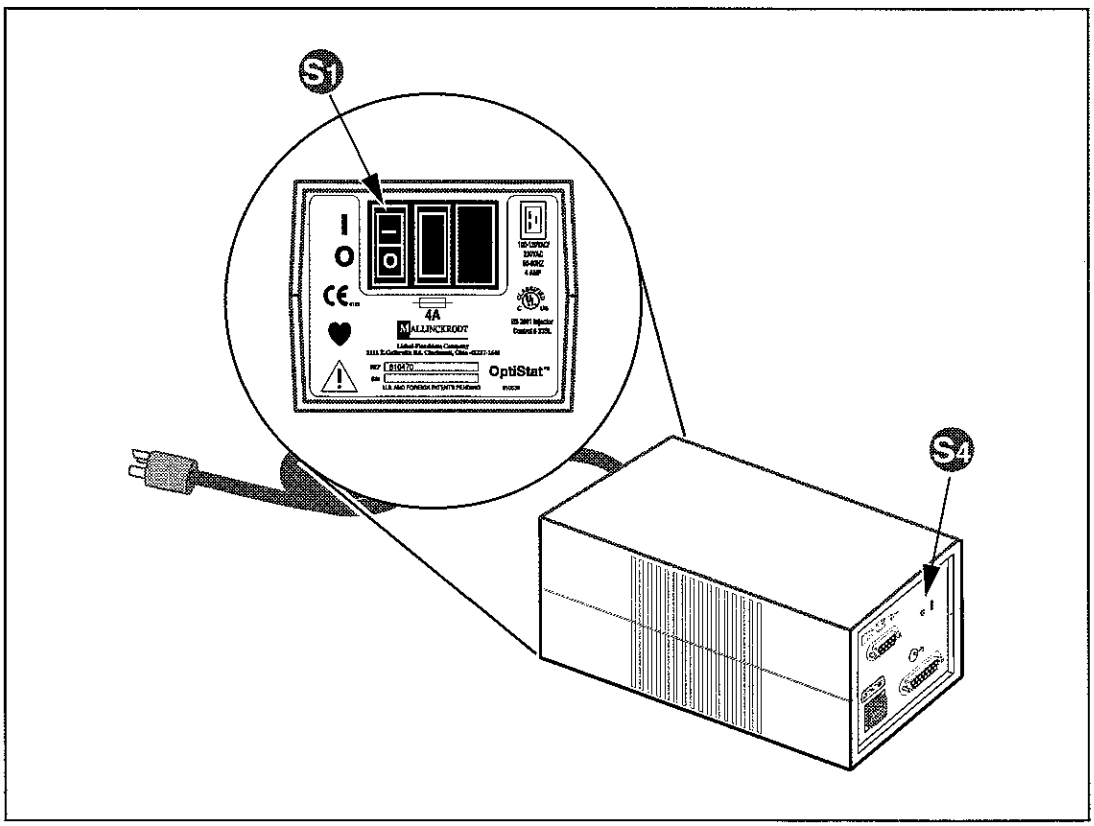


Figure 1-2-1 Power Supply Switch

Power-Up Self Test

When the OptiStat unit is switched "ON," it automatically performs a series of power-up tests to monitor the status of all injector systems.

During power-up, the seven segment display on the Powerhead and Console will be illuminated for three seconds. Make sure all of the segments are functional. Also check to be sure the inject status indicator [P2] is functioning properly. See Figure 1-3-1.

⚠ CAUTION! ⚠

In order to prevent power-up diagnostic errors, do not activate keys for 15 seconds after switching unit "ON"

If the drive ram is not at its fully retracted position, the Console and Powerhead display will show error code UE 003. See Figure 1-2-2. Retract the ram to the home position using the purge/retract trigger [P5] to clear the error code.

The default value at power-up for flow rate is 2.5-ml/sec. The default volume is the pre-set maximum programmable volume.

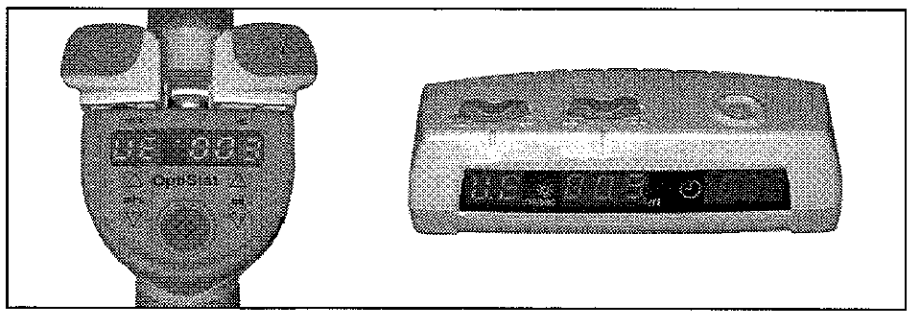


Figure 1-2-2 Error Code UE003

1.2.2 TURNING THE SYSTEM POWER OFF

If the unit will not be used for an extended period of time, the unit should be turned to the "OFF" position with the Power Supply Power Switch [S1]. Refer to Figure 1-2-1.

To place the unit in stand by mode, a key [S2] located in the rear of the console should be used. Refer to Figure 1-3-3. The console and powerhead will be turned off but the power supply will remain on.

1.3 CONTROLS AND INDICATORS

1.3.1 POWERHEAD CONTROLS AND INDICATORS

Refer to Figure 1-3-1.

P1 Syringe Clamps

P2 Powerhead Display

P3 Powerhead Keypad

P4 Status Indicator

Color	Function
Green	Enabled
Multi-color Sweep	Injecting
Red	Error/Fault
Amber	Paused
Off	Inactive

P5 Purge-Retract Trigger

P6 125-ml Pre-filled Syringe (shown), Also accepts all partial pre-filled sizes and the L-F 130-ml empty.

P7 Drive Ram

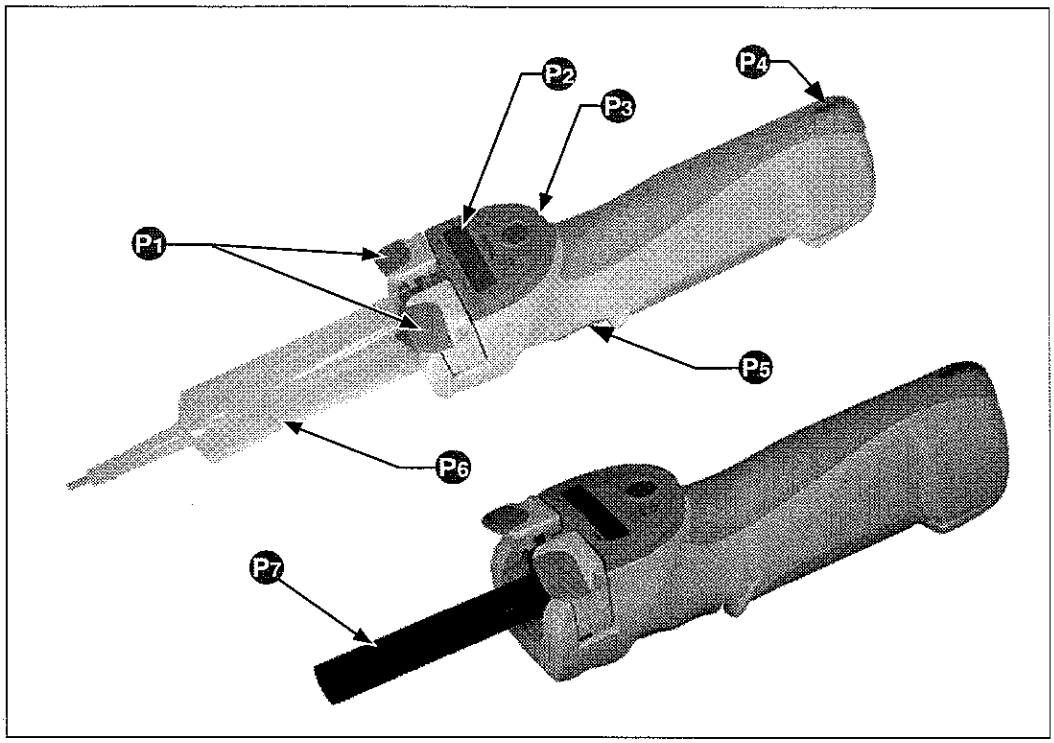


Figure 1-3-1 Powerhead Controls and Indicators

1.3.2 POWERHEAD KEYPAD

Refer to Figure 1-3-2

P7 Flow Rate Display- acceptable programming values are 0.1 to 6.0 ml/sec. Displays actual Flow Rate during the injection and achieved Flow Rate at end of injection

P8 Volume Display- displays maximum volume upon power-up or remaining volume while injecting.

P9 Increase/Decrease Flow Rate Keys- momentary activation changes the value by 0.1 ml/sec. Pressing and holding down the key changes the value at a faster rate.

P10 Increase/Decrease Volume Keys- momentary activation changes the value by 1 ml. Pressing and holding down the key changes the value at a faster rate. The Increase Volume Key is used to select the Maximum Volume value.

P11 Start/Stop Key- pressing this key will start an enabled injection or pause a running injection. The key is green when enabled and blue when running.

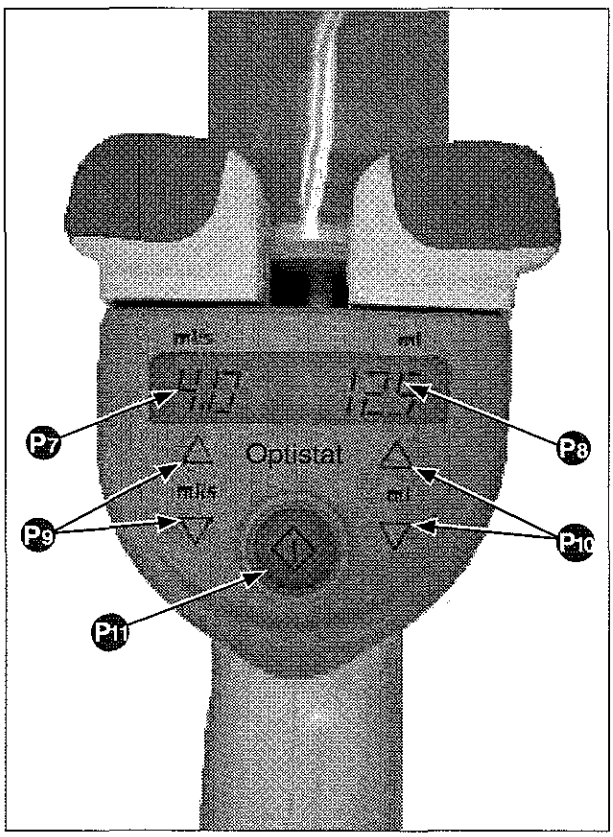


Figure 1-3-2 Powerhead Keypad

1.3.3 CONSOLE KEYS AND INDICATORS

Refer to Figure 1-3-3.

C4 Injection Status Indicator

Color	Function
Green	Enabled
Multi-color Sweep	Injecting
Red	Error/Fault
Amber	Paused
Off	Inactive

C7 Flow Rate Display-acceptable programming values are 0.1 to 6.0 ml/sec. Displays actual Flow Rate during the injection and achieved Flow Rate at end of injection

C8 Volume Display- displays maximum volume upon power-up or remaining volume while injecting.

C9 Increase/Decrease Flow Rate Keys-momentary activation changes the value by 0.1 ml/sec. Pressing and holding down the key changes the value at a faster rate.

C10 Increase/Decrease Volume Keys- momentary activation changes the value by 1 ml. Pressing and holding down the key changes the value at a faster rate. The Increase Volume Key is used to select the Maximum Volume value.

C11 Start/Stop Key- pressing this key will start an enabled injection or pause a running injection.

C12 Scan Delay Timer- Indicates elapsed time from start of injection.

C13 On/Off Key- (on back, not shown)- Switched power "OFF" to the Control Console and Powerhead. Does not switch main power supply "OFF".

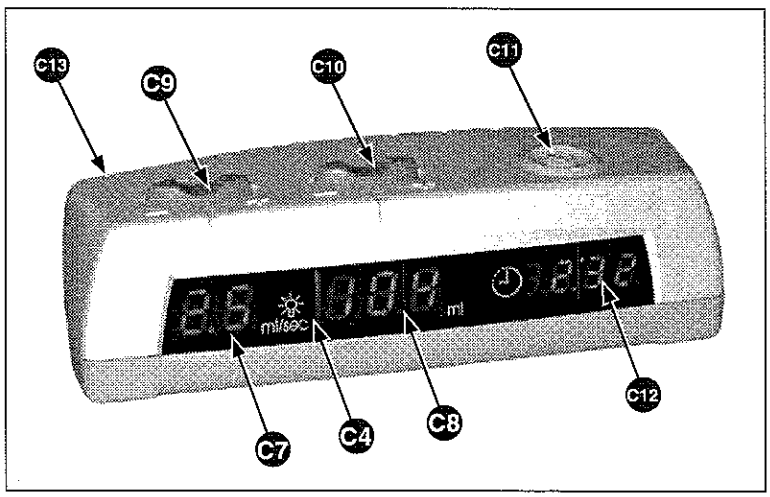


Figure 1-3-3 Keys and Indicators of the Console

1.3.4 POWER SUPPLY

Refer to Figure 1-3-4.

S1 Main Power On/Off Switch

S2 AC Power Receptacle *(Item #6 in Chapter 2)*

S3 Fuse holder plug

S4 Power Indicator- Illuminates green when power is "ON".

S5 Connector for 75' (23M) Powerhead extension cable *(Item #4 in Chapter 2)*

S6 Connector for 7' (2M) Console Cable *(Item #9 in Chapter 2)*

S7 Interface Connector- Used to interface dual OptiStat injectors or OptiStat to an L-F CT9000ADV. Check with Customer Service for compatibility.

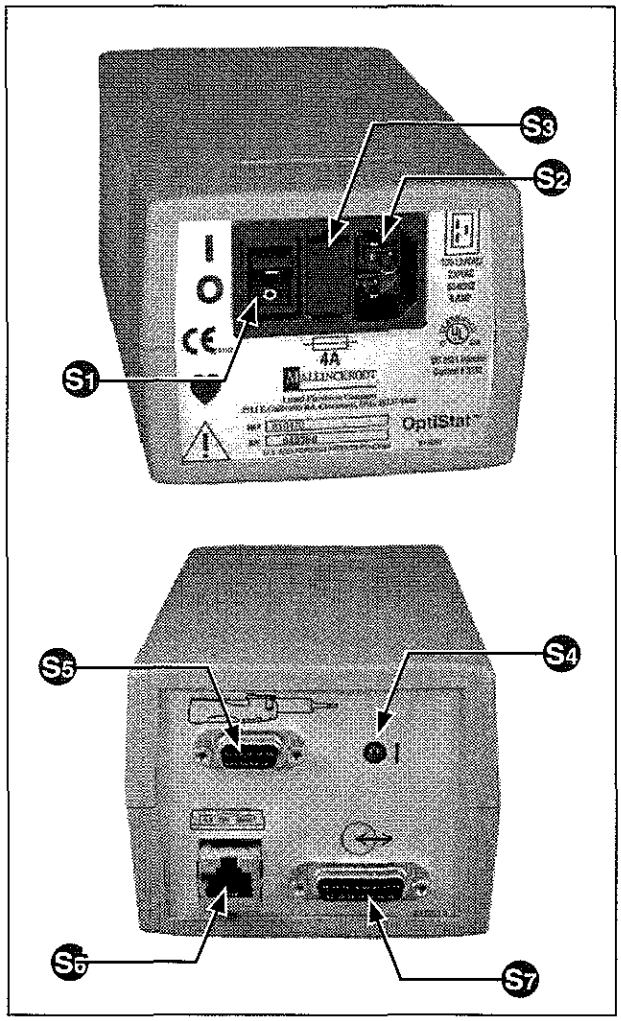


Figure 1-3-4 Controls and Indicators of the Power Supply

1.4 SETTING VALUES

The flow rate and injection volume can be changed at any time except during delivery of an injection.

1.4.1 SETTING THE MAXIMUM PROGRAMMABLE VOLUME

Refer to Figure 1-4-1.

The OptiStat accommodates the Liebel-Flarsheim 130 ml empty syringe and the Mallinckrodt pre-filled Ultraject syringe. The Ultraject syringe volume is available in 125 ml full fill, and is also available in partial pre-filled sizes of 100 ml, 75 ml and 50 ml. ***When using partial pre-filled syringes, it is important that the programmed volume of the OptiStat does not exceed the pre-fill volume of the syringe.***

To ensure the programmed volume does not exceed the pre-fill volume, the OptiStat can be pre-set to one of the following values: UF 130 (unfilled 130 ml syringe), PF 125 (pre-filled 125 ml), PF 100 (pre-filled 100 ml), PF 75 (pre-filled 75 ml), or PF 50 (pre-filled 50 ml). This action tells the OptiStat to allow only the selected volume as a maximum programmable volume. Setting the maximum programmable volume is accomplished as follows:

1. At the powerhead or the console, increment the volume to the maximum value. Depress and hold the volume increment key [P or C] for about three seconds until "PF" or "UF" flashes in the flow rate display.
2. Press the volume increment or decrement key to the desired value (UF 130, PF 125, PF 100, PF 75, or PF 50).
   NOTE: Be sure to pre-set the OptiStat into 130 ml mode (UF 130) when using the 130 ml syringe. In order to safeguard against air injections, the 130 ml empty syringe has a different filling/enable process than the pre-filled syringes *(see section 1-5 Enabling the Injector*.
3. Return to the program mode by pressing the flow rate increment or decrement key [P or C] or allowing the unit to "time out" after 10 seconds. Now the maximum programmable volume value is set. The OptiStat will remain with this maximum programmable volume until the value is modified by repeating this setup sequence.

⚠ CAUTION! ⚠

It is important that the programmed volume of the Optistat does not exceed the pre-fill volume of the syringe. Otherwise, equipment damage can occur.

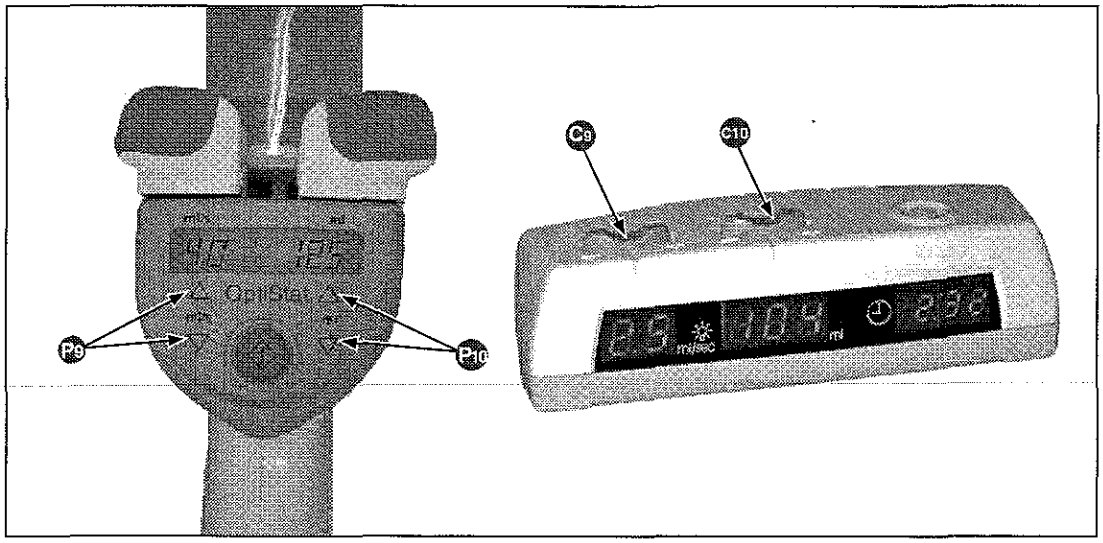


Figure 1-4-1 Powerhead Volume Keys

1.4.2 SETTING THE VOLUME

The desired volume is programmed from the powerhead or the console by using the volume increment and decrement keys [P10 or C10].

Pressing the key and releasing it will change the value by 1 ml. Holding the key down will change the volume more rapidly. The OptiStat will remain set at the last programmed value until it is changed. If the unit is switched "OFF", the maximum programmable volume will be displayed.

1.4.3 SETTING THE FLOW RATE

The desired flow rate in milliliters per second is programmed from the powerhead or the console by using the flow rate increment and decrement keys P9 or C9].

Pressing the button and releasing it will change the value by 0.1 ml/sec. Holding the key down will change the flow rate more rapidly. The OptiStat will remain set at the last programmed value until it is changed. If the unit is switched "OFF", the default flow rate will return to 2.5 ml/sec.

1.5 ENABLING THE INJECTOR

The danger of air embolism is always present when injecting into the circulatory system. The enabling sequence for the OptiStat Contrast Delivery System is designed to help prevent air injections. In order to enable the OptiStat for an automatic injection, the following syringe loading sequence and the manual air purge sequence must be performed in order to ensure a safe injection. ***Note: the enable sequence in itself does not guarantee that all air has been completely removed from the system. The operator is responsible for ensuring that all air has been completely evacuated from the syringe and tubing prior to delivering the injection.***

1.5.1 LOADING THE 125 ML PRE-FILLED SYRINGE

1. If the drive ram [P7] is not home, move to the fully retracted position.
2. Inspect the syringe and contents for irregularities prior to loading.
3. Attach extension tubing to the syringe.

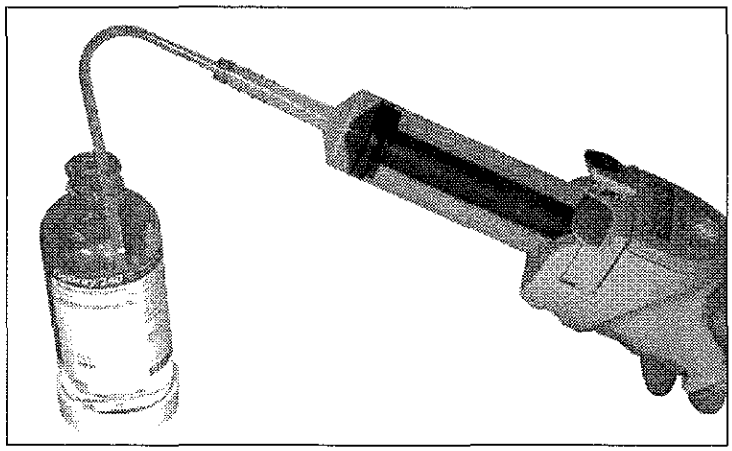
Note: Refer to syringe pack instructions when attaching extension tubing.

4. Open syringe clamps [P8] and firmly slide the syringe into position *(Make sure the clamps close completely).*

1.5.2 LOADING/FILLING THE 130 ML EMPTY SYRINGE

The OptiStat also allows the use of the Liebel-Flarsheim 130 ml empty syringe (Part Number 600172). Since the syringe is empty, the enable sequence is different than the 125 ml in order to permit a filling sequence.

1. If the ram is not home, move to the fully retracted position.
2. Inspect syringe for irregularities prior to loading.
3. Open syringe clamps [P1] and firmly press the syringe into position *(Make sure the clamps close completely)*.
4. Move drive ram to the fully extended position by holding the Purge/Retract trigger [P5].
5. Attach "J" shaped Handifil straw supplied with the syringe.
6. Fill syringe to the desired volume. The drive ram must be retracted the equivalent of at least 25 ml during the fill sequence to allow the injector to auto-enable.



7. Remove "J" shaped straw and attach the extension tubing to the syringe.

Note: Refer to syringe pack instructions when attaching extension tubing.

1.5.3 MANUAL AIR PURGE SEQUENCE

1. Air bubbles trapped in contrast media MUST be removed to prevent injection of an air embolism into the patient. To remove bubbles, slowly rotate powerhead to allow the air pocket to pick up the air bubbles on the sides of the syringe. Point tip of syringe upward to allow the air bubbles to rise to the tip.
2. Using the purge trigger [P5], advance the plunger to push the air pocket out the syringe tip and out through the tubing. The plunger must move forward an equivalent of 2 ml to indicate to the injector that an attempt was made to purge the air.

1.5.4 INJECTOR ENABLED

1. Once the plunger is moved an equivalent of 2 ml, the indicator light [P4] on the rear of the unit will illuminate green signifying the unit is now enabled for auto-inject. ***The operator is responsible to ensure that the air has been completely evacuated from the system.*** Be sure that the air has been completely evacuated from the system.
2. A slot on the underside of the Powerhead is provided to secure the extension tubing.

1.5.5 CHECK FOR PATENCY

The OptiStat allows the retract trigger to pull the plunger back in order to check the patency of the I.V. catheter. Once the plunger is retracted, the indicator light will extinguish and the OptiStat will no longer be enabled. The OptiStat will re-enable by moving the plunger forward using the purge trigger. Do not allow blood to remain in the I.V. access line.

⚠ DANGER! ⚠

DANGER! BLOOD CLOT HAZARD! Do not allow blood to remain in I.V. access line.

1.5.5 SAFETY TIP

After the OptiStat is enabled (as indicated by the illuminated green light [P4] on the powerhead and console [C4]), hold the tip of the syringe downward or place the OptiStat into its holder. This safety precaution reduces the possibility of an air emboli. Any small remaining air bubbles will tend to float away from the tip and will not be injected into the patient.

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1.6 STARTING/STOPPING AN INJECTION

1.6.1 DANGERS/WARNINGS/CAUTIONS

⚠ DANGER! ⚠

Follow all manufacturers guidelines and do not operate any part of the OptiStat system within 6 inches (15-cm) of a pacemaker and or defibrillator.

⚠ DANGER! ⚠

DANGER! AIR EMBOLISM HAZARD!

Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiStat Contrast Delivery System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

1.6.2 STARTING THE INJECTION

There are two ways to perform the injection:

1. Manually by using the purge/retract trigger [P5] on the powerhead.
2. Automatically using the start button [P1 or C1] either on the powerhead or the console.

Manual Injection with Purge/Retract Trigger

Refer to Figure 1-6-1.

The purge trigger [P5] can be used to inject flow rates greater than 0.5 ml/sec by fully depressing the front of the trigger and holding it down. This will inject at the programmed rate and volume. A flow rate less than what is programmed can be accomplished by only partially depressing the purge trigger.

The indicator light on the console [C1] and powerhead [P1] will sweep through a color spectrum to indicate that the OptiStat is injecting.

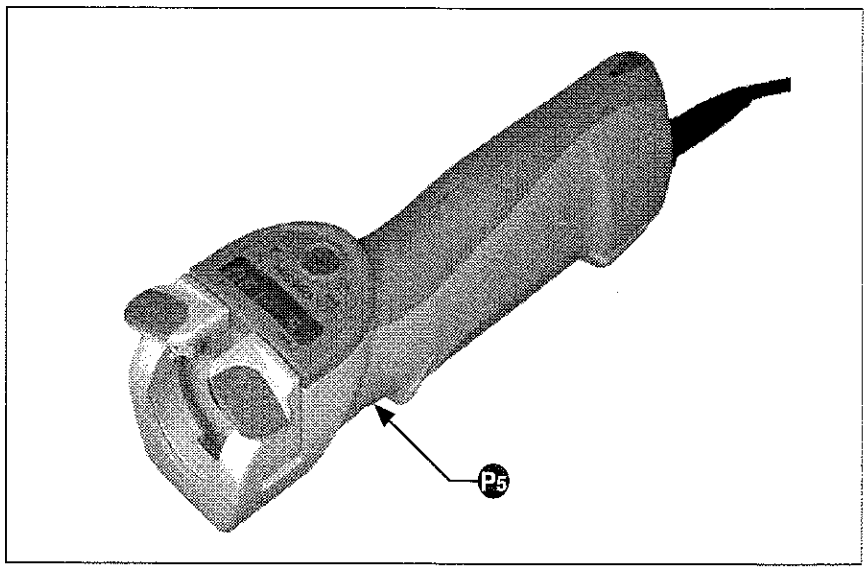


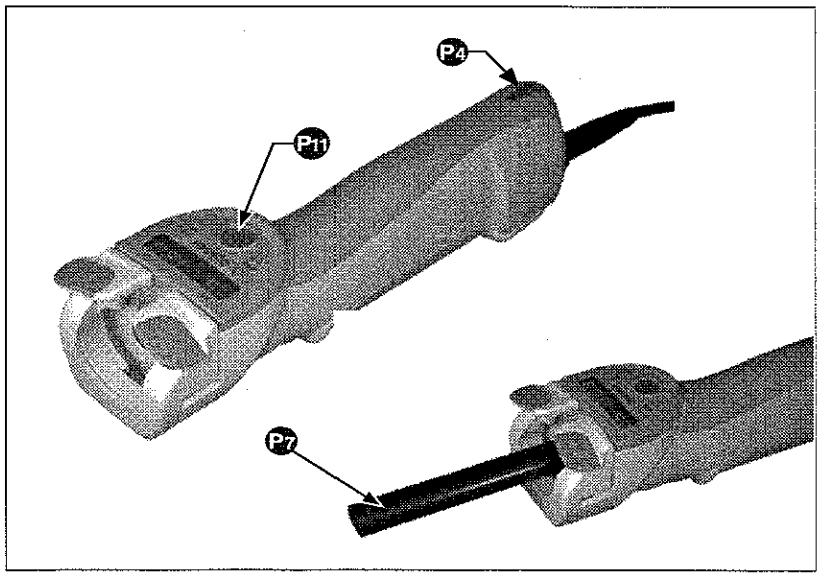
Figure 1-6-1 Manual Injection P5 trigger

Automatic Injecting Using the Start Key

The injection can be initiated by pressing the start key [P11 or C11] either on the powerhead or the console.

The indicator light on the console [C4] and powerhead [P4] will sweep through a color spectrum to indicate that the OptiStat is injecting.

Once the injection is initiated, the timer on the Console [C12] starts counting up. The timer will run for 20 minutes from the start of the injection. The timer can be used to indicate the elapsed time from the start of the injection to enable the operator to start the CT scanner or X-ray at the appropriate time. The timer is reset to "—:—" when the Drive Ram [P7] is retracted.



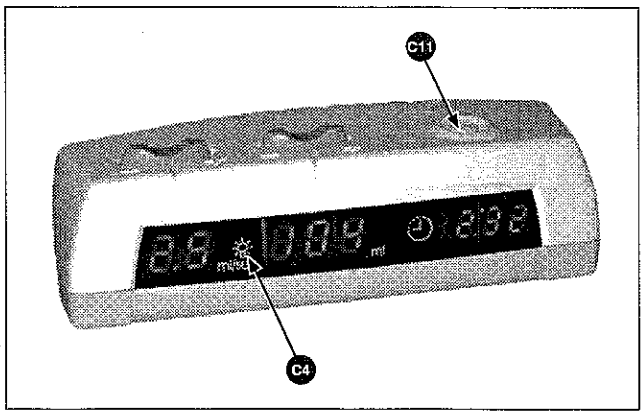


Figure 1-6-2 Automatic Injection Start Keys

1.6.3 PAUSING AN INJECTION

Refer to Figure 1-6-2.

An injection may be immediately halted by pressing any button on the console or powerhead as well as activating the Purge/Retract trigger [P5]. When the OptiStat is paused, the indicator lights on the Console [C7] and Powerhead [P7] will flash amber.

While the injection is paused, the values for the flow rate and programmed volume can be changed from either the Powerhead or the Console. The timer continues to run from the time the initial injection was started.

1.6.4 RESTARTING A PAUSED INJECTION

The injection can be restarted by pressing the Start key on the console or the powerhead. The achieved values displayed after completion of the re-started injection represent only the average flow rate and volume achieved since the restart.

1.6.5 DISPLAYING ACHIEVED VALUES

The Achieved Values for average flow rate and delivered volume are flashed on both the console and the powerhead at the completion of the injection. These values revert to the programmed rate and volume when the ram retract is initiated at the powerhead. NOTE: During the injection, the display indicates the actual flow rate. After the injection has completed, the display indicates the achieved average flow rate. Please note that the achieved average flow rate may be slightly lower than the actual flow rate displayed during the injection.

1.6.6 RE-ENABLING AN INJECTION

Upon completion of an injection, the injector can be re-enabled by depressing the purge trigger [P5] or the Start key [P1 or C1].

Note: The achieved values displayed after completion of the re-enabled injection are not cumulative.

1.6.7 TERMINATING AN INJECTION

Any key on the powerhead and console can be used to pause or stop an injection. Retracting the ram [P7] will clear the delivered values and the OptiStat will be required to go through the enable sequence (including syringe replacement) in order to be re-enabled for another injection.

1.7 REMOVING THE SYRINGE

⚠ DANGER! ⚠

REMOVE SYRINGE PROMPTLY

Failure to remove syringe/ backer plate after completion of a procedure can lead to an inadvertent injection of air. Used syringes and backer plates should be promptly removed from the OptiStat injector immediately after a procedure is completed to avoid accidental re-use of the empty syringe. Injecting air can cause patient injury or death.

To remove the syringe proceed as follows:

1. Retract the syringe plunger to the full home position.
2. Push down on both or one syringe clamp.
3. The syringe can be easily lifted out.

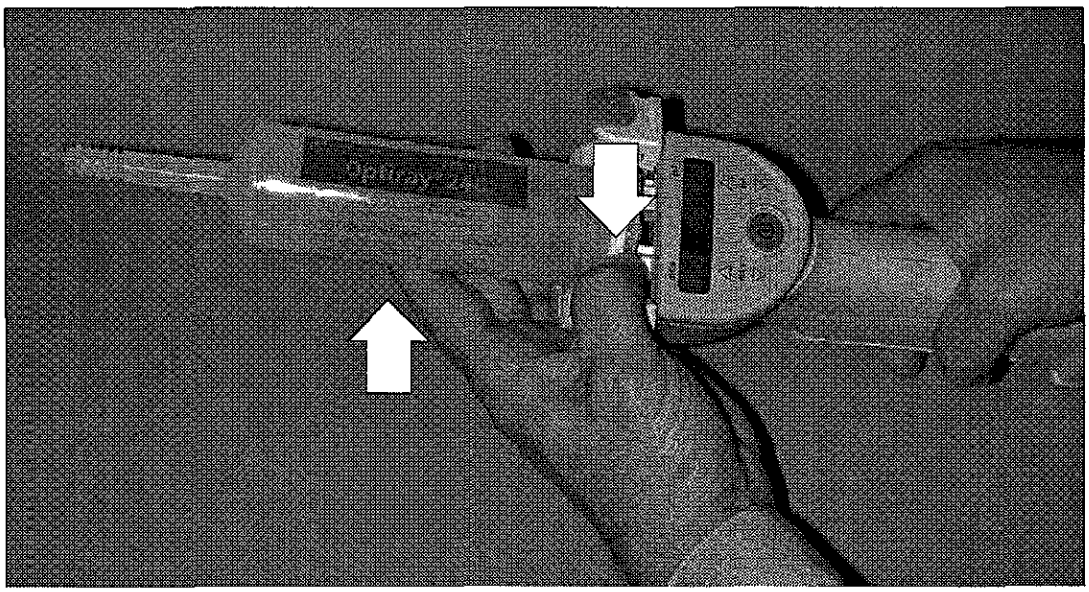


Figure 1-7-1 Syringe Removal

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1.8 OPTIONAL ACCESSORY OPERATING INSTRUCTIONS

1.8.1 OPTISTAT/OPTISTAT KIT P/N 810615

Note: To interface two OptiStat injectors, Consoles must be installed.

Prior to injecting, both OptiStat Injectors must be enabled as indicated by the green status indicator on the Powerhead and Console (refer to this Manual for details).

Program each OptiStat to the desired flow rate and volume. Either the "A" or "B" injector can be started first, the second injection will start immediately after successful completion of the first injection. The injection can be paused by pressing any button on the Powerhead or Console of the running unit.

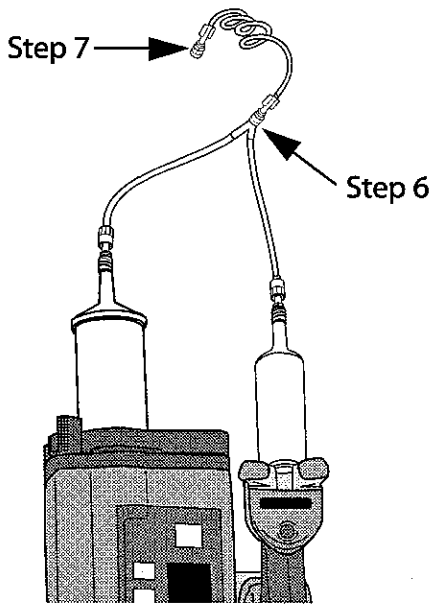
The second OptiStat will not start if a fault condition occurs during the first injection. Each injector can also be operated individually provided the second OptiStat injector is not enabled.

1.8.2 DUAL HEAD CT9000ADV/OPTISTAT OPERATOR INSTRUCTIONS

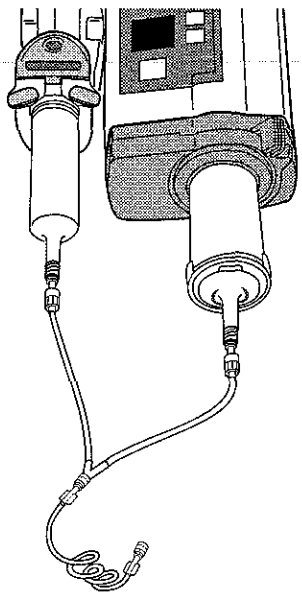
Typical Saline Chase Injection Set-up

For this sample injection, the CT9000ADV contains the contrast syringe, and the OptiStat contains the saline syringe. The CT9000ADV can use the prefilled Ultraject syringe or the user filled 200 ml syringe (P/N 800096). The OptiStat can use the user filled 130 ml syringe (P/N 600172) or the Ultraject 125 ml pre-filled saline syringe when available.

1. Make sure the CT9000ADV "Scan Delay" is set to 000.
2. Tilt the powerhead so the syringes are pointed up.
3. Fill syringes if not already pre-filled.



4. Install "Y" tubing (P/N 810555)
5. Install Coiled Tubing (P/N 601195) for 60"
6. *Purge OptiStat Saline up to intersection of the "Y". The green light on the back of the OptiStat will illuminate Green indicating that it is "Enabled".
7. *Purge CT9000ADV to end of coiled tubing.
8. Tilt the powerhead so the syringes are pointed down so any possible remaining air in the syringe will not be injected into the patient.



9. Enable CT9000ADV. Multi-phasic injections are permissible.
10. Start injection. Stopping or pausing the CT9000ADV is permissible.
11. OptiStat will start after successful completion of the CT9000 Injection.
12. At the end of the injection, remove the "Y" tubing from both syringes before pulling back the syringe plungers. The "Y" tubing contains one-way check valves that will cause a vacuum to be created in the syringe if the plunger is pulled back.

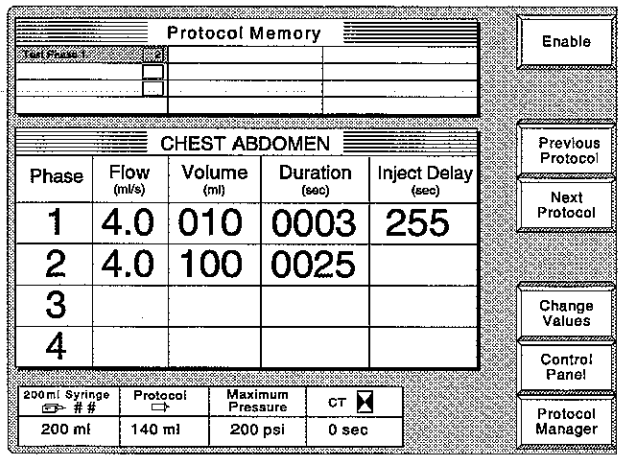
*It may be desirable to fill the 60' coiled tubing with saline instead of contrast. In that case, purge the ADV to the intersection of the "Y" tubing and purge the OptiStat to the end of the coiled tube.

Test Injection

Changing the protocol of a dual injection.

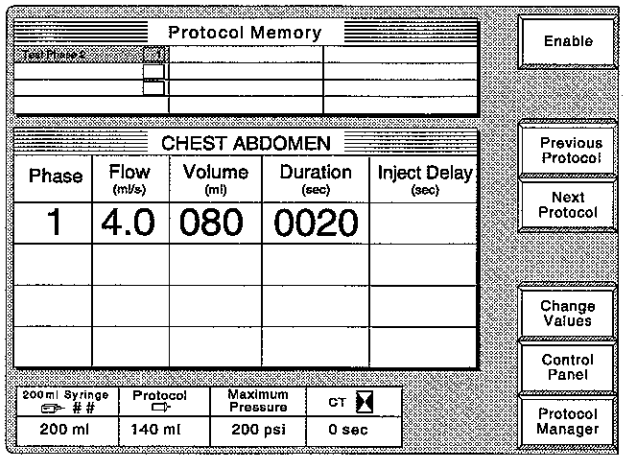
It may be desirable to change the second phase of a multi-phasic injection based on parameters from a test injection.

1. Set up a multi-phasic injection based on the most common scenario. For example;



2. Follow the set-up instructions for a dual injection previously defined.
3. Phase 1 is the test or scout injection. At the end of phase 1, the injector will go into a 255 second inject delay. When the phase 1 injection is complete and the injector is in the "Inject Delay" mode, press "Stop" on the CT9000ADV console. It can be stopped indefinitely during the inject delay. Stopping the CT9000ADV will not initiate the OptiStat.

4. If the test injection indicates the pre-defined parameters are appropriate, press start. Phase 2 will start immediately. At the end of the second phase, the OptiStat will start.
5. If the parameters in phase 2 are not appropriate, press "Disable" and "Exit" out of the protocol. Go to another stored protocol as defined in the following example. (note: Set the Inject Delay to 0 so the OptiStat starts immediately upon completion of the injection).



6. The Volume and Flow Rate can be changed as needed. Once they are set, enable the CT9000ADV and "Start" the injection at the appropriate time. The OptiStat will start upon completion of the injection.

> ***Warning!*** *At the end of the dual injection, it is important to remove the "Y" tubing from both syringes before pulling back the syringe plungers. The "Y" tubing contains one-way check valves that will cause a vacuum to be created in the syringe if the plunger is pulled back.*

2 SERVICE

2.1 OVERVIEW

Your system is composed of interchangeable modules that are serviced by an exchange program.

2.1.1 TROUBLESHOOTING PRINCIPLES

The OptiStat Contrast Delivery System is equipped with self-diagnostics which will display a Fault Code if it detects a problem with the unit.

In the event of a failure, first check the obvious, power switch (S1), and cable connections including the line cord. Check for physical problems: cracks, broken pieces, noises. Also, for safety reasons, some functions will not operate if the proper initiation process has not been followed. A User Error Code will be displayed on the Powerhead or Console to identify these problems.

2.1.2 CARE OF THE UNIT

Powerhead

The Powerhead is not waterproof so do not submerge or allow fluids to pool on the surfaces. The Powerhead may be cleaned by using an all-purpose household cleaner. Dried contrast can be removed with warm water. Spray the cleaner on the cloth, then gently buff the key pads clean. Do not use disinfectants containing n-Alkyl or Ammonium Chlorides.

⚠ CAUTION! ⚠

Disinfectants containing n-Alkyl or Ammonium Chlorides can degrade the structural integrity of the OptiStat case.

Control Console

The Console screen may be dusted by using a lint-free cloth. The key pad of the Console may be cleaned by using an all-purpose household cleaner. Spray the cleaner on the cloth, then gently buff the key pads clean.

Power Supply

Clean the exterior of the Power Supply by spraying a cloth with an all-purpose household cleaner, then gently wipe clean.

2.1.3 PERFORMANCE VERIFICATION

The scheduled time frame to conduct this check will be determined by sight policy.

Flow Rate

Program the OptiStat injector for a 100 ml injection. Time the duration of the injection. Refer to the table below:

Programmed Flow Rate	Expected Duration	Actual Duration
1 ml/sec	100 seconds ± 2%	
3 ml/sec	33.3 seconds ± 2%	

Volume

Refill a 125 ml or 130 ml syringe with cold water (4°C is optimum). Purge all of the air out of the syringe. Program the OptiStat injector for a 100 ml at 3 ml/sec injection. Weigh the delivered volume on an accurate scale. The weight of the delivered volume must be within 98 to 102 grams.

2.2 TROUBLESHOOTING CODES

2.2.1 USER CODES (UE XXX)

If the user attempts to operate the injector in an unsafe manner, the letter "UE" will appear in the flow rate display. Also, a three digit number will appear in the volume display. These errors are correctable by following the instructions in the operations chapter of this manual.

Code	Error
UE 001	User attempted to start an injection from the Powerhead when the injection is not enabled
UE 101	User attempted to start an injection from Remote Console when the injector is not enabled
UE 002	User attempted to move the ram forward with the syringe clamp open
UE 003	Ram not at home position after power-up. Fully depress Retract Trigger until RAM is fully retracted.

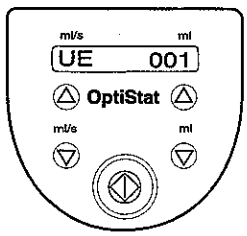


Figure 2-2-1 User Error Code

2.2.2 FAILURE CODES (F 0XX)

To isolate an equipment problem, a set of Failure codes will be displayed on the Powerhead and Console (if present).

The letter "F" will appear in the flow rate display. Also, a three digit number will appear in the volume display. The first digit of this number identifies which subsystem has failed, and the remaining digits identify the type of failure. For example: 0XX Powerhead, 1XX Console, 3XX Power Pack.

Should a failure code appear, cycle power ON and OFF to ensure the code is repeated. Also, check all connections. If the failure code repeats. Call customer service for further instructions and arrange for a replacement. (See Return Policy).

Refer to figure 2-2-2 for display presentation

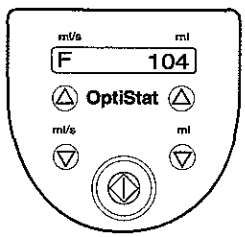


Figure 2-2-2 Failure Code Presentation

Powerhead Failure Codes (F 0XX)

Code	Description	Possible Corrective Action
F 001	Microcontroller CPU Fail	Cycle power, if problem repeats replace Powerhead
F 002	Program Flash Memory CRC Fail	Same as above
F 003	Data Flash Memory CRC Fail	Same as above
F 004	RAM Memory Fail	Same as above
F 005	Quad Timer Fail	Same as above
F 006	A/D Converter Fail	Same as above
F 007	PWM Fail	Same as above
F 008	Interrupt Controller Fail	Same as above
F 009	Clock PLL Fail	Cycle power, check all connections, if problem repeats, replace Powerhead
F 010	Microcontroller Watchdog Reset	Same as above
F 012	Low Voltage	Cycle power, if error repeats, replace Powerhead
F 013	Powerhead button stuck ON	Check Powerhead button cover. Check Powerhead buttons, Cycle power, if problem repeats, replace Powerhead
F 014	Nonvolatile Memory failure	Cycle power, if problem repeats replace Powerhead
F 020	+24VDC Power Supply Fail	If Console displays error code 120, replace Power Supply. If no error appears on Console, replace Powerhead
F 021	+5VDC Power Supply Fail (+5VDC Power Supply out of tolerance)	Same as above
F 022	Soft Power Down Fault	If displayed continously, turn off power, disconnect Console and power on. If error repeats, replace Power Supply. If error does not repeat, replace Console.
F 030	Motor or encoder malfunction	Check fluid path for obstruction, if error repeats, replace Powerhead.
F 031	Motor or encoder malfunction	Check fluid path for obstruction, if error repeats, replace Powerhead.
F 032	Motor Relay Fail (cut-out relay fail, relay stock open or closed	Cycle power, if problem repeats, replace Powerhead
F 033	Motor failure (motor over current detected)	Same as above
F 034	Motor failure (current detected when motor not enabled)	Check fluid path for obstruction, if error repeats, replace Powerhead.

Powerhead Failure Codes (Con't) (F 0XX)

F 040	Powerhead Start switch failure (one or both start switches are active)	Check keypad on Powerhead, verify switch is not sticking if error repeats, replace Powerhead
F 041	External Start Signal Fault	Turn off power, disconnect Console, Turn on power, if error returns, check cables, if cables are good, replace Powerhead.
F 042	Remote Start Failure	Same as above
F 050	Home sensor failure (no home position signal detected when ran encoder indicates that the injector ram is at the home position)	Recalibrate Home position. See calibration section. If problem repeats, replace Powerhead
F 051	Purge/Retract Trigger failure (zero position out of tolerance)	Recalibrate Purge/Retract trigger. If problem repeats, replace Powerhead
F 052	Retract Trigger failure	Replace Powerhead
F 053	Expel Trigger failure	Replace Powerhead
F 054	Enable Trigger failure	Replace Powerhead
F 060	Achieved Flow Rate out of Tolerance	Check fluid path for obstruction. If problem repeats, replace Powerhead
F 061	Pressure Limit	Check fluid path for obstruction. If problem repeats, replace Powerhead
F 062	Flow Rate Limit	Check fluid path for obstruction. If problem repeats, replace Powerhead
F 070	Powerhead - Remote Console Communication failure (Powerhead only)	Dual head error, check interface cables, check Console and Powerhead cables, If problem repeats, Call Service
F 080	Retract Trigger Calibration out of Tolerance	Recalibrate Purge/Retract trigger. See calibration section. If problem repeats, replace Powerhead
F 081	Expel Trigger Calibration out of Tolerance	Same as above
F 082	Trigger Enabled Calibration out of Tolerance	Same as above
F 083	Syringe Clamp Calibration out of Tolerance	Same as above
F 084	Home Position Calibration out of Tolerance	Same as above

Console Failure Codes (F 1XX)

Code	Description	Possible Corrective Action
F 101	Microcontroller CPU Fail	Cycle power, if problem repeats replace Console
F 102	Program Flash Memory CRC Fail	Same as above
F 103	Data Flash Memory CRC Fail	Same as above
F 104	RAM Memory Fail	Same as above
F 105	Quad Timer Fail	Same as above
F 106	A/D Converter Fail	Same as above
F 107	PWM Fail	Same as above
F 108	Interrupt Controller Fail	Same as above
F 109	Clock PLL Fail	Cycle power, check all connections, if problem repeats, replace Console
F 110	Microcontroller Watchdog Reset	Same as above
F 113	Control Panel Button Stuck ON	Check Console buttons, Cycle power, if problem repeats, replace Console
F 114	Nonvolatile Memory Failure	Cycle power, if problem repeats replace Console
F 120	+24VDC Power Supply Fail	If Powerhead displays error code 020, replace Power Supply. If no error appears on Powerhead, replace Console
F 121	+5VDC Power Supply Fail (+5VDC Power Supply out of tolerance)	Same as above
F 122	Soft Power Down Fault	Cycle power, if problem repeats replace Console
F 140	Console Start switch failure (one or both start switches are active)	Check Console, start switch. Cycle power, if problem repeats replace Console
F 142	Remote Start Failure	Cycle power, if problem repeats replace Console
F 175	Remote Console-Power Pack Communication failure (Remote Console only)	Turn off power, disconnect Console. Turn power on, if error code appears on Powerhead, power off and check Powerhead cables. If problem repeats,Call service.

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Power Pack Failure Codes (F 3XX)

Code	Description	Possible Corrective Action
F 370	Dual Injector Interface failure	Check all cable connections; cycle power. If problem repeats, replace Console

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2.3 PARTS

2.3.1 FIELD REPLACEABLE UNITS (FRU)

	Item	FRU Description	Part Number
		Final Assembly, OptiStat Contrast Delivery System with Console (Domestic)	810000
		Final Assembly, OptiStat Contrast Delivery System without Console (Domestic)	810001
		Final Assembly, OptiStat Contrast Delivery System with Console (International)	810005
		Final Assembly, OptiStat Contrast Delivery System without Console (International)	810006
*	1	Final Assembly, Powerhead	810150
	2	Powerhead Coiled Cord (10': 2.5M)	810195
	3	Wall Plate Assembly	810546
	4	Powerhead Extension Cable (75":19M)	810545
*	5	Final Assembly, Power Supply	810470
	6	Line Cord (10': 2.5M) USA 110VAC	800918
	6	Line Cord (10': 2.5M) European	800935
	7	Kit, Interface, OptiStat to OptiStat	810615
	7	Kit, Interface, OptiStat to CT9000ADV	810721
		Cable Ass'y, OptiStat Interface	810625
		PCB Ass'y, Universal Interface Board	800889-1
		Cable, OptiStat to CT9000/ADV	810630
*	8	Final Assembly, Console	810025
	9	Console Cable (7': 1.8M) **No substitution allowed**	810140
	12	Assembly, Syringe Clamp	810430
	13	Keypad Cover	810335
		English Manual, Operator, Service & Installation	810600

Figure 2-3-1 Field Replaceable Units

2.3.2 ACCESSORIES AND OPTIONAL EQUIPMENT

Item	Description	Part Number
2	Powerhead UnCoiled Cord (20': 6.1M)	810194
11	Wall Powerhead Mount	810160
14	Dual Head Remote Stand Powerhead Mount (OptiStat to CT9000 ADV)	810706
15	IV pole Powerhead Mount	810192
16	Clamp, IV Pole (Clamp Only)	810190
	CD Language Manual Package	810605

Figure 2-3-1A Accessories And Optional Equipment

* The powerhead, power supply and console may be labeled with different part numbers than listed here. However, these FRU part numbers are used for ordering purposes.

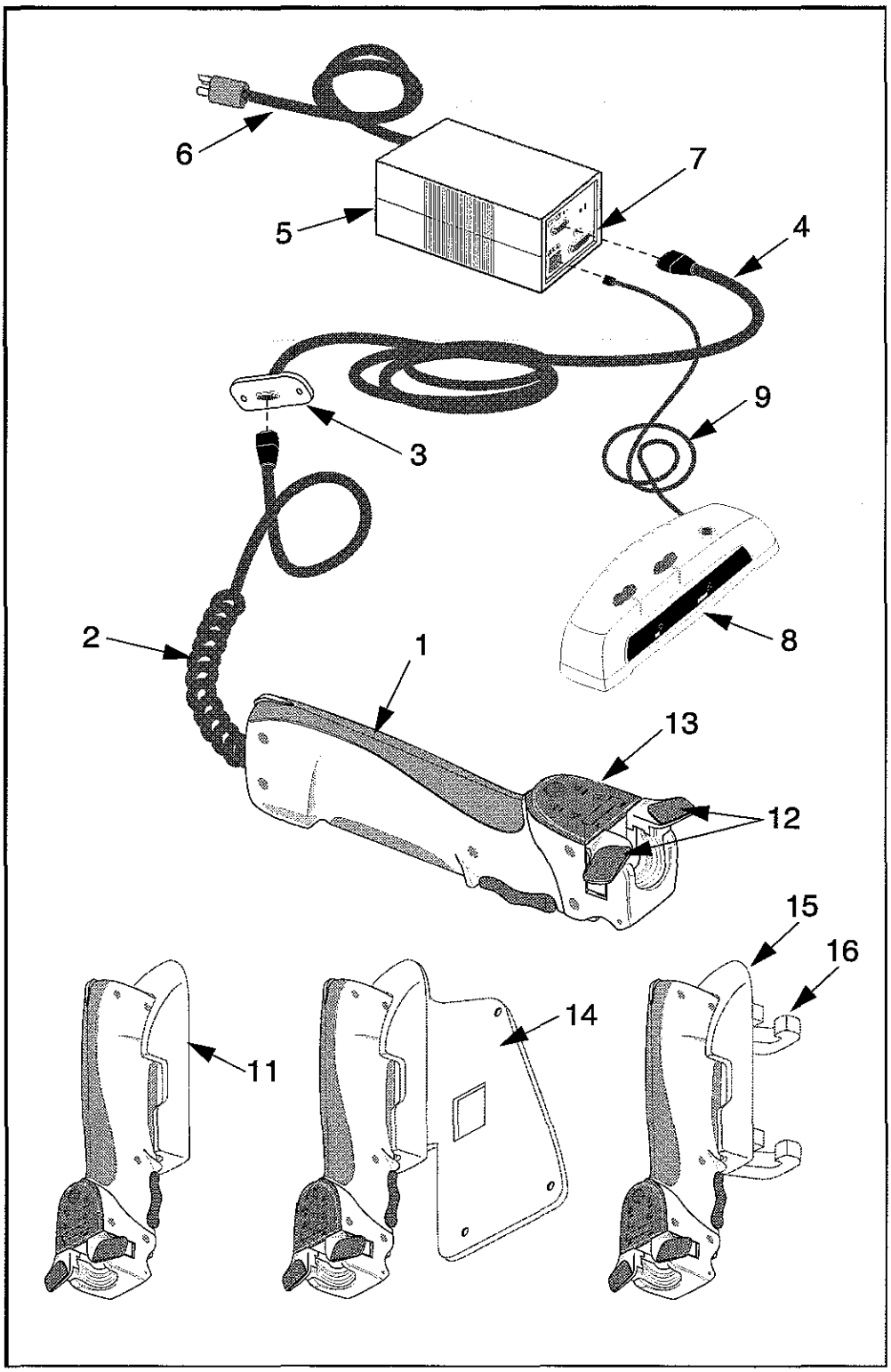
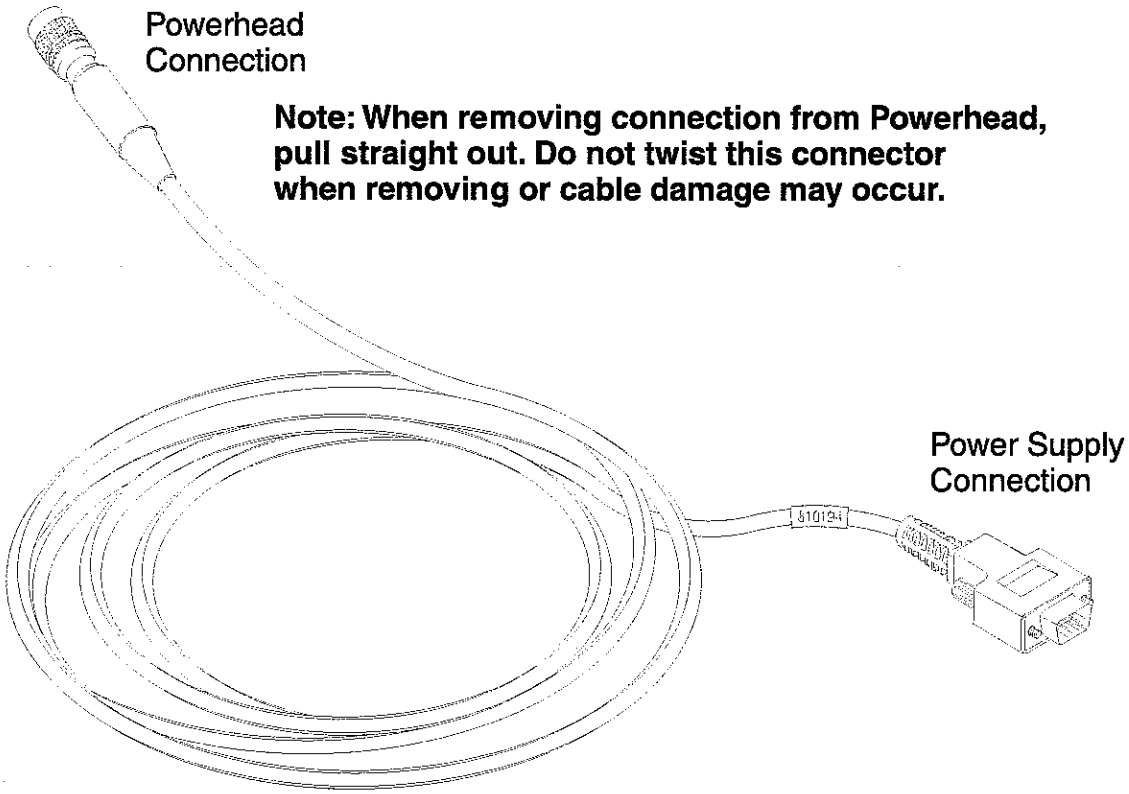


Figure 2-3-2 FRU Item Numbers

2.3.3 CABLE PINOUTS

ITEM 2 POWERHEAD/CONSOLE CABLE



Note: When removing connection from Powerhead, pull straight out. Do not twist this connector when removing or cable damage may occur.

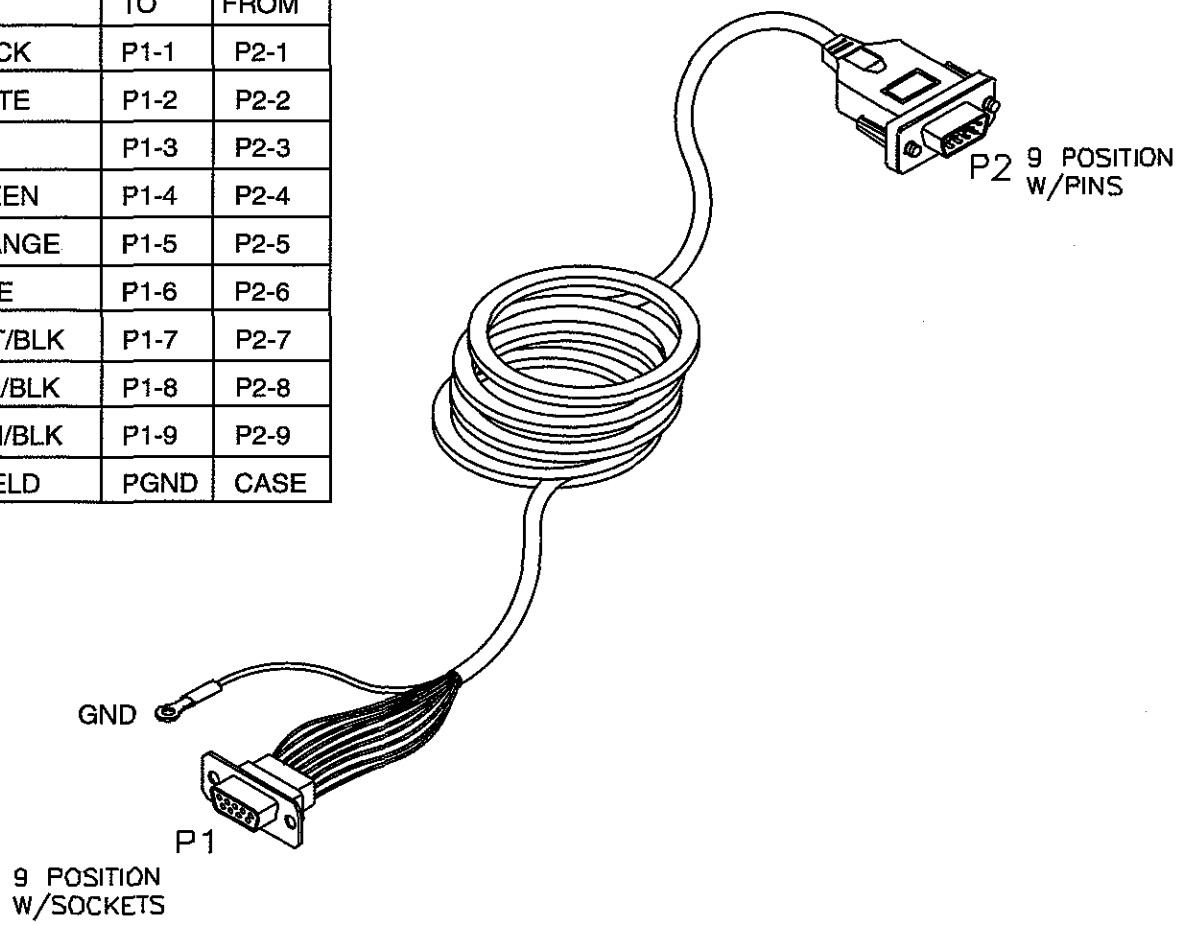
PINOUTS

Powerhead	Console
P1 Shield Gnd	P1 Sheild Gnd
P2	C2
P3	C3
P4	C4
P5	C5
P6	C6
P7	C7
P8	C8
P9	C9

ITEM 4 POWERSUPPLY/WALL PLATE - EXTENSION CABLE

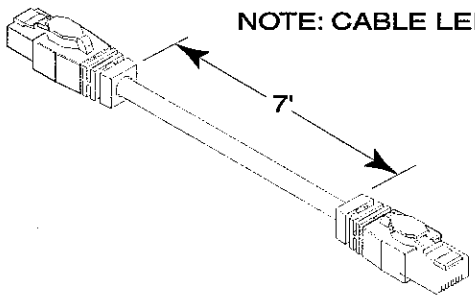
PINOUTS

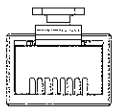
	TO	FROM
BLACK	P1-1	P2-1
WHITE	P1-2	P2-2
RED	P1-3	P2-3
GREEN	P1-4	P2-4
ORANGE	P1-5	P2-5
BLUE	P1-6	P2-6
WHT/BLK	P1-7	P2-7
RED/BLK	P1-8	P2-8
GRN/BLK	P1-9	P2-9
SHIELD	PGND	CASE



ITEM 9 POWER SUPPLY/CONSOLE CABLE

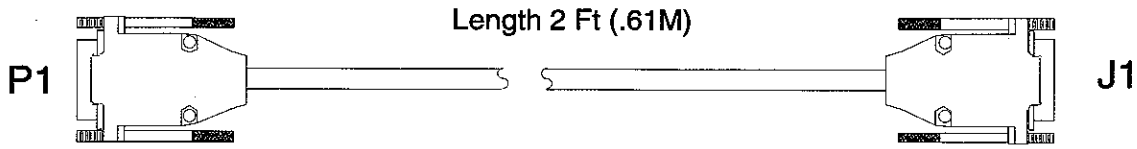
NOTE: CABLE LENGTH CAN NOT EXCEED 7 FEET





WIRING CHART		
PIN	COLOR	PIN
1	WHITE/ORANGE	1
2	ORANGE	2
3	WHITE/GREEN	3
4	BLUE	4
5	WHITE/BLUE	5
6	GREEN	6
7	WHITE/BROWN	7
8	BROWN	8

OPTISTAT TO OPTISTAT CABLE (810614)



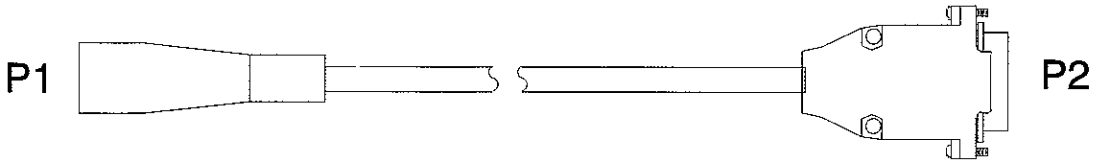
P1 PINS
2, 4, 6, 8, 12
ARE JUMPERED
TOGETHER

CABLE PINOUTS

P1		J1
3	Brown	11
5	Orange	10
7	Green	9
9	Violet	7
10	Gray	5
11	White	3
13	Black	13

J1 PINS
2, 4, 6, 8, 12
ARE JUMPERED
TOGETHER

OPTISTAT TO CT9000ADV CABLE (810630)



P2 PINS
12, and 13
ARE JUMPERED
TOGETHER

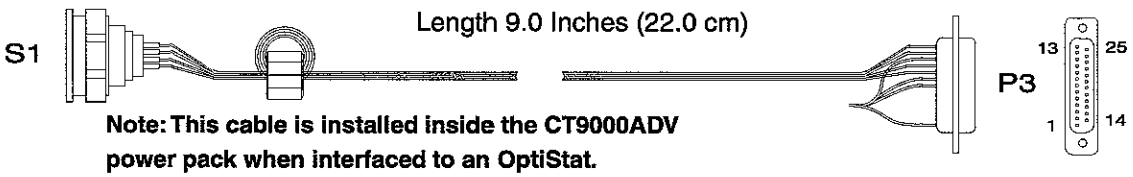
PINOUTS

P1		P2
1	Black	8
Tab	Drain	Housing
3	Red	10
4	Green	9
2	Brown	11

CABLE LENGTHS

Part No.	Lengths
810630	3Ft (.91M)
810010	50Ft (15 M)
810020	100Ft (30 M)

OPTISTAT INTERFACE CABLE (810625)



Note: This cable is installed inside the CT9000ADV power pack when interfaced to an OptiStat.

P3 PINS
1, 7, 8, 13
ARE JUMPERED
TOGETHER

PINOUTS

S1		P3
1	Red	11
2	Orange	2
3	Yellow	20
4	Green	21

2.3.4 SYRINGE CLAMP REMOVAL /INSTALLATION (ITEM 12)

Refer to Figure 2-3-3.

Make sure the ram is at the home position.

The Syringe Clamp Assembly contains a retaining clip. To remove the assembly from the Powerhead, use two small screwdrivers and simultaneously push on each clip through the two access holes provided.

Note: Always reinstall a new syringe clamp. Removing the Syringe Clamp Assembly will damage the retaining clips.

To install a new clam assembly, simply push the clamps in place until a snap is felt.

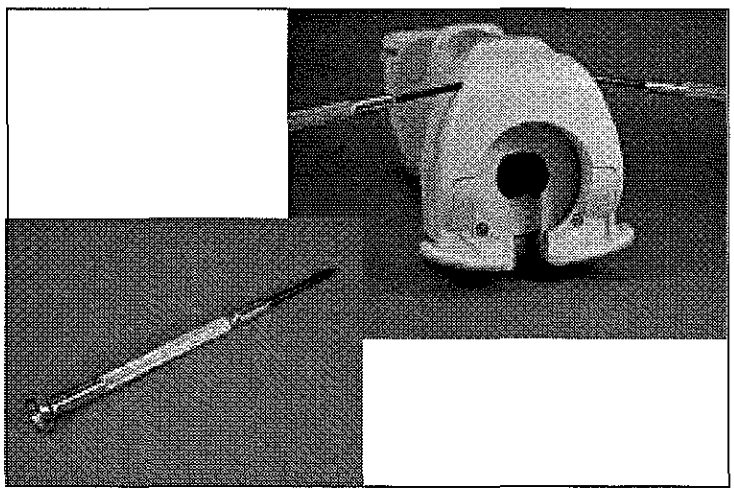


Figure 2-3-3 Syringe Clamp Assembly Removal

2.4.1 RETURN POLICY

Follow the instructions below to get a replacement FRU.

Replacement FRU

A failed Powerhead, Console, or Power Supply must be returned to the factory. The packaging for the replacement unit will be used to return the failed unit. The customer will be invoiced for the cost of the returned part. If the failed component is returned within 30 days, they will receive an exchange credit. Failed parts for the other FRU's do not need to be returned unless specifically requested.

Returns

Call customer support (800) 877-0791 for a return authorization (RA) number.

The following information must be recorded in order to obtain the RA number:

Serial Number of the component (if applicable)
Type of failure
What may have caused the failure
PO number (if applicable)

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2.5 CALIBRATION

The OptiStat Contrast Delivery System has several sensors which were calibrated at the factory and should not require re-calibration. However, if the unit exhibits a problem, the re-calibration sequence may be performed.

Note: Calibration should only be performed by qualified trained service personnel.

⚠ WARNING! ⚠

Calibration errors can cause erratic functioning of the OptiStat.

2.5.1 ACTIVATING CALIBRATION MODE

1. Turn OFF the system.
2. Remove any syringe from the Powerhead.
3. Power ON the system.
4. After a few seconds, the LED's will display the software version as shown in Figure 1. Simultaneously press the Volume increment and decrement keys until the numbers "0.0" appears in the left side of the display (Figure 2).

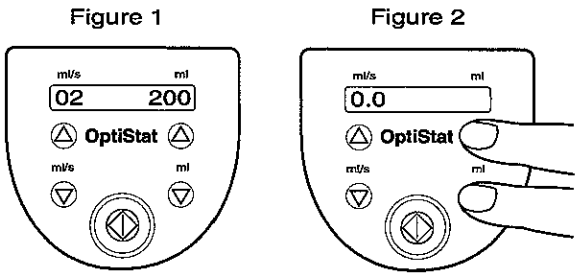
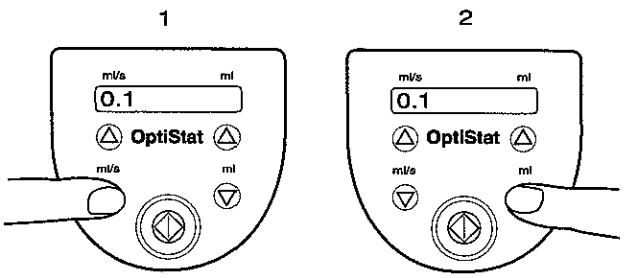


Figure 2-5-1 Activating Calibration Mode

2.5.2 EXITING CALIBRATION MODE

1. Press flow rate increment or decrement key to select code 0.1.
2. Press the volume decrement key to exit calibration.
   The unit is now calibrated and is ready to be used.



⚠ WARNING! ⚠

Only perform calibration functions described in this section.

2.5.3 CALIBRATION CODES

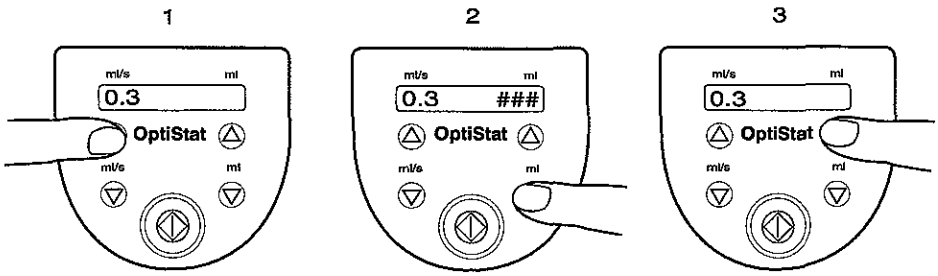
The procedures which follow will calibrate the following sensors:

- Powerhead Purge/Retract Trigger
- Powerhead Ram Home Position
- Syringe Clamp

Calibration codes are selected by using the flow rate (P9) keys. Refer to figure 2-5-1.

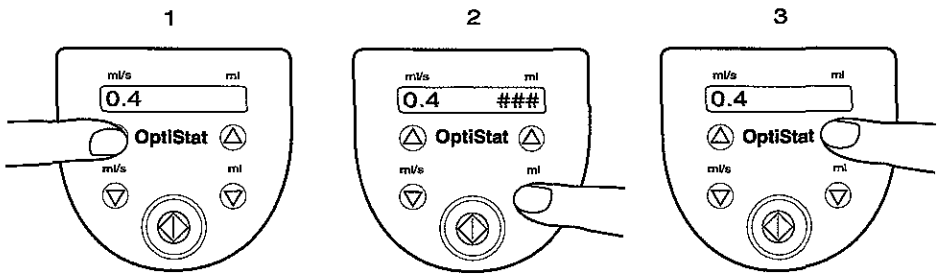
Code 0.3 Purge/Retract (Purge)

1. Press flow rate increment or decrement key to select code 0.3. Fully depress and *hold* front purge trigger.
2. Press the volume decrement key to display setting. [Range: 300-330]
3. Press the volume increment key to accept setting and exit code 0.3.



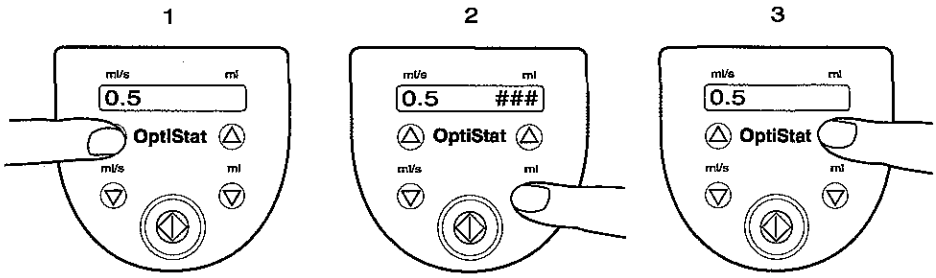
Code 0.4 Purge/Retract (Purge)

1. Press flow rate increment or decrement keyto select code 0.4. Fully depress and *hold* front purge trigger.
2. Press the volume decrement key to display setting. [Range: 300-330]
3. Press the volume increment key to accept setting and exit code 0.4.



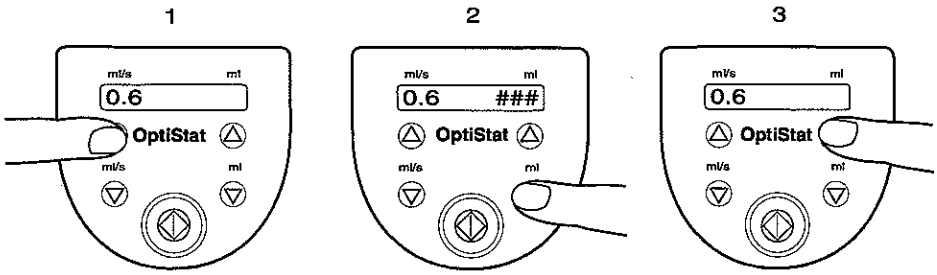
Code 0.5 Purge/Retract (Off)

1. Press flow rate increment or decrement key to select code 0.5. Purge/retract trigger should be in the neutral position.
2. Press the volume decrement key to display setting. [Range: 008-033]
3. Press the volume increment key to accept setting and exit code 0.5.



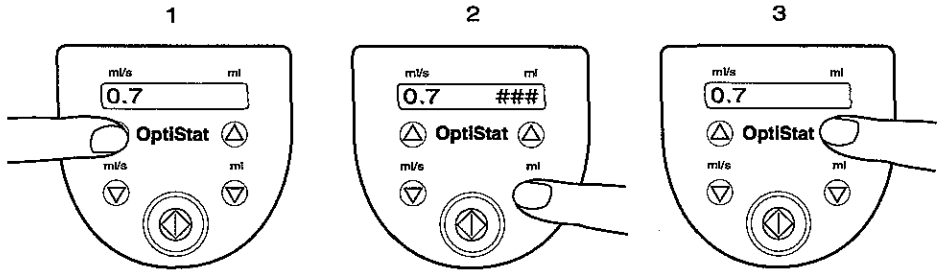
Code 0.6 Purge/Retract (Off)

1. Press flow rate increment or decrement key to select code 0.6. Purge/retract trigger should be in the neutral position.
2. Press the volume decrement key to display setting. [Range: 120-250]
3. Press the volume increment key to accept setting and exit code 0.6.



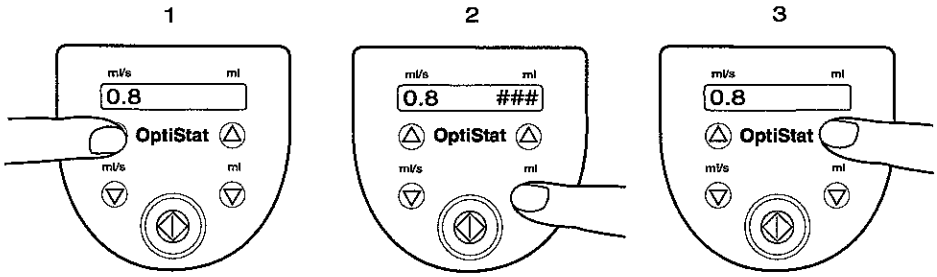
Code 0.7 Purge/Retract (Off)

1. Press flow rate increment or decrement key to select code 0.7. Purge/retract trigger should be in the neutral position.
2. Press the volume decrement key to display setting. [Range: 310-330]
3. Press the volume increment key to accept setting and exit code 0.7.



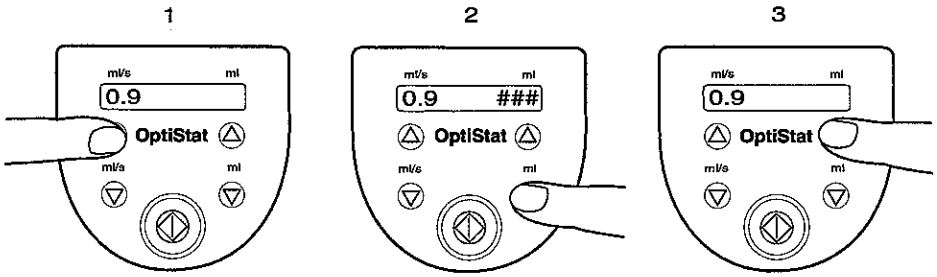
Code 0.8 Purge/Retract (Retract)

1. Press flow rate increment or decrement key to select code 0.8.
   Fully depress and *hold* retract trigger.
2. Press the volume decrement key to display setting. [Range: 008-015]
3. Press the volume increment key to accept setting and exit code 0.8.



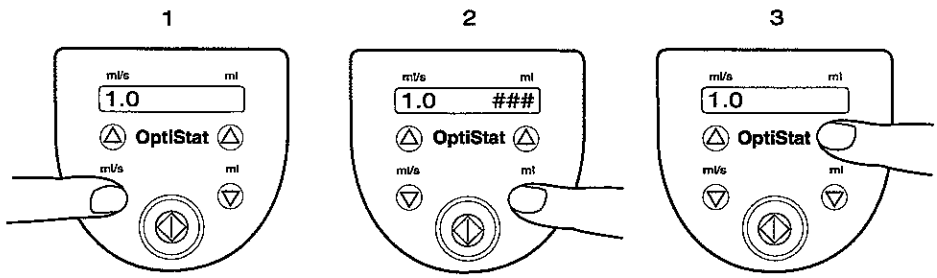
Code 0.9 Purge/Retract (Retract)

1. Press flow rate increment or decrement key to select code 0.9.
   Fully depress and *hold* retract trigger.
2. Press the volume decrement key to display setting. [Range: 008-100]
3. Press the volume increment key to accept setting and exit code 0.9.



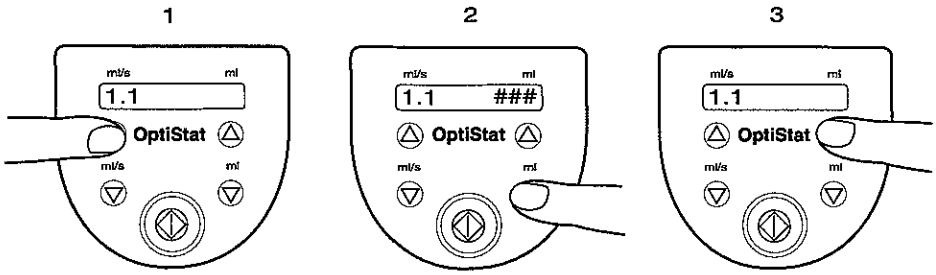
Code 1.0 Ram Home Position

1. Press flow rate increment or decrement key to select code 1.0.
2. Press the volume decrement key.
   Using the Purge/Retract trigger, position the drive ram flush to the front of injector. [Range: 200-300]
3. Press the volume increment key to accept setting and exit code 1.0.



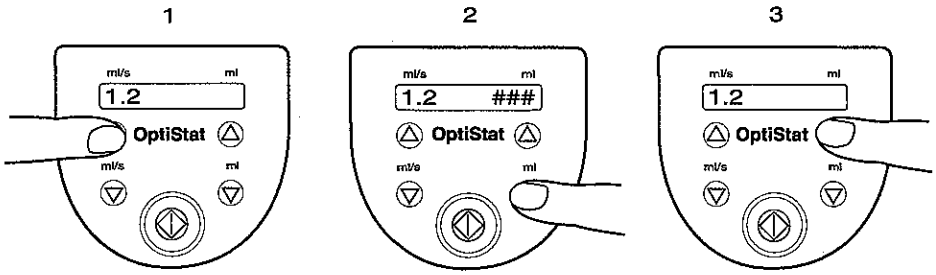
Code 1.1 Syringe Clamp (Open)

1. Press flow rate increment or decrement key to select code 1.1.
   Open left clamp (clamp positioned above ml/s).
2. Press the volume decrement key to display setting. [Range: 150-200]
3. Press the volume increment key to accept setting and exit code 1.1.



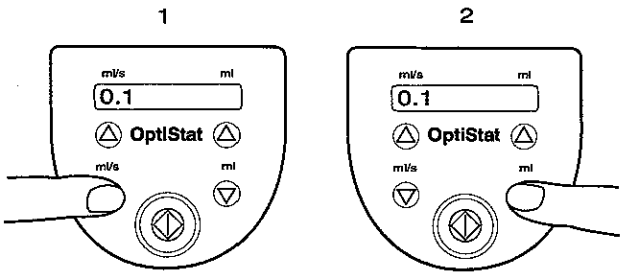
Code 1.2 Syringe Clamp (Closed)

1. Press flow rate increment or decrement key to select code 1.2.
   Close left clamp.
2. Press the volume decrement key to display setting.
   [Clamp Open value (i.e. code 1.1) + at least 50]
3. Press the volume increment key to accept setting and exit code 1.2.



Code 0.1 Exit Calibration

1. Press flow rate increment or decrement key to select code 0.1.
2. Press the volume decrement key to exit calibration.
   The unit is now calibrated and is ready to be used.



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3 INSTALLATION

3.1 OVERVIEW

The purpose of this chapter is to provide procedures for installing your OptiStat Contrast Delivery System.

To prevent installation problems, the Power Supply, Powerhead, and Console all communicate through cables with unique connectors. These cables allow sharing of power and transfer of information. For unit connection information, refer to Figure 3-1-1.

⚠ CAUTION! ⚠

Power must be off before connecting or disconnecting any of the unit's cabling. Connecting cables after the unit is powered may cause false error code generation and damage to the unit.

⚠ CAUTION! ⚠

Always comply with local electrical codes during installation.

3.1.1 SITE PLANNING

Site Planning and room preparation are the responsibilities of the purchaser. The following should be considered fundamental to pre-installation activities.

- Location of all components should be reviewed in order to prevent conflicts with other equipment, such as, door openings, service and operational clearances of other equipment, etc.
- All Electrical Work must comply with Federal, State, and Local Code Requirements which may exceed recommendations shown in this documentation.
- Hospital must supply 230/115VAC grounded outlet within 5 feet (1.5 meters) of Power Supply Box.
- Provide appropriate wall penetrations per code for cable(s) installation. Hospital should consult with design professionals where applicable.
- The dimensions and weights for all components are specified. The Hospital is responsible for all Structural Work, including, but not limited to, structural members, shelving, etc. required for component(s) installation.
- All hardware, j-boxes (to withstand 30 lb/14 kg), conduit, support members, etc. are to be supplied and installed by Hospital and/or Hospital contractor.
- Installation of components and cabling is the responsibility of the Hospital.

3.1.2 POWER SUPPLY

The Power Supply is designed to sit on the floor or any horizontal surface. It is equipped with a 10' line cord, so in must be located in the vicinity of the main supply power. For CT installations, the control room is the recommended location.

The power cord connection at the power supply accept between 100VAC (50/60 Hz), and 240VAC (50/60 Hz) without modification. The unit will automatically sense the input voltage during the power-up sequence.

When the Power Supply is turned ON, the LED located in the upper right-hand corner will be illuminated green.

⚠ WARNING! ⚠

Only use the supplied power cord to connect power. Use of other power cords could result in damage to equipment or cause personnel injury. Units installed outside of the United States must use hospital approved power cords.

3.1.3 POWERHEAD WALL HANGER

The Powerhead Wall Hanger should be mounted in a convenient location to hang the Powerhead during procedures.

The hanger bracket can conform to slightly curved surfaces, and is supplied with a high-strength foam tape. To ensure and adequate bond, clean the mounting surface with alcohol, and make sure the surface is free of loose paint or particulates. Also, screw holes are provided for extra security.

⚠ WARNING! ⚠

DO NOT place screws in any electrical/medical device.

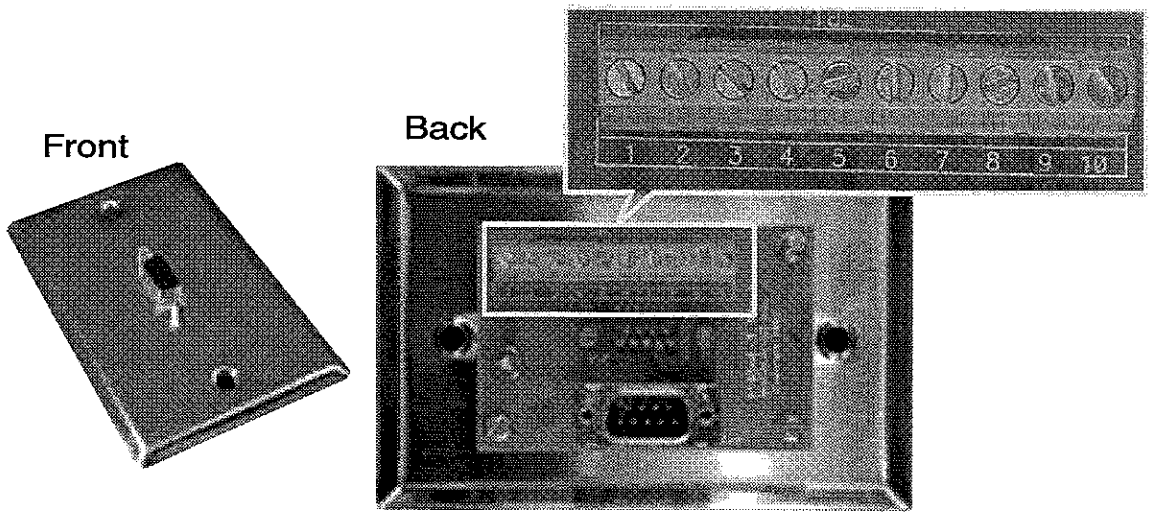
Additional hangers as well as optional IV pole mounts are available for greater flexibility of mounting locations.

3.1.4 POWERHEAD WALL PLATE CONNECTION

A 9 pin D-shell connection sends and receives information to and from the Powerhead through a 75 feet (22.8 meters) extension cable. The Powerhead Extension cable is plenum rated so in many cases it does not need to be routed in conduit. However, it is the customers responsibility to check local codes for installation requirements.

The Powerhead extension cable terminates at the Wall Plate. The cable connects to a 9 pin D-shell connection. However, the cable can be shortened and terminated by using a terminal block. Check local codes to see if an electrical box is required. Refer to Figure 3-1-1 for terminal information.

The Wall Plate mounting must be able to withstand a 30-lb (14 kg) pull. The 10 feet (3.0 meters) Powerhead coiled cord is then attached to the Wall Plate connector. Also, ensure all connector locking screws are secure.



TB1: 1 ← CGND — (BLK)
TB1: 2 ← DGND — (WHT)
TB1: 3 ← NOT USED — RED
TB1: 4 ← CANH — GRN
TB1: 5 ← CANL — ORG
TB1: 6 ← START — (BLUE)
TB1: 7 ← +24VDC — (WHT/BLK)
TB1: 8 ← +24VDC — (RED/BLK)
TB1: 9 ← DGND — (GRN/BLK)
TB1: 10 ← NC

Figure 3-1-1 Wall Plate Terminal Block

3.1.5 CONTROL CONSOLE (OPTIONAL)

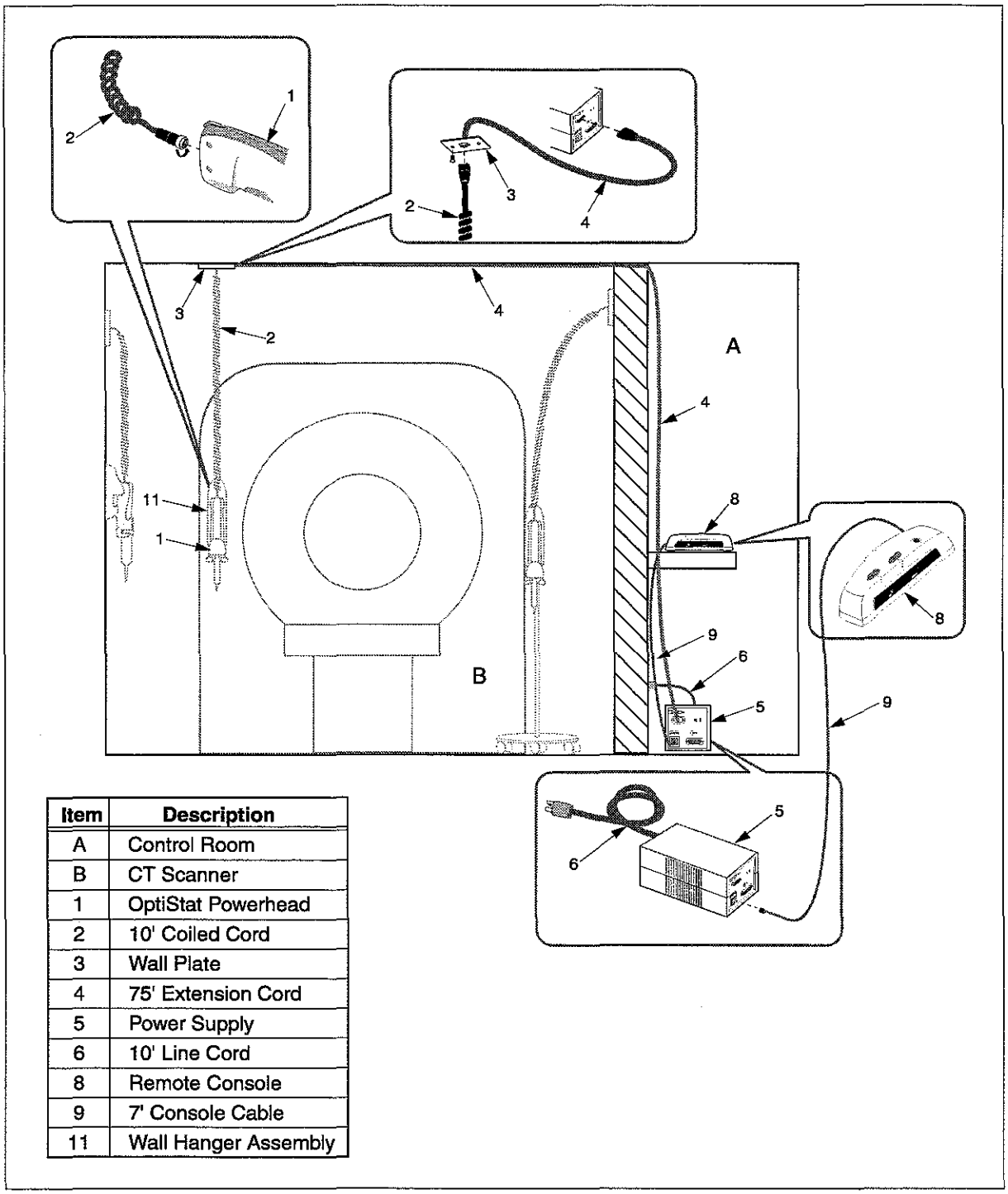
The optional Control Console is small enough to rest on any horizontal surface like a desktop or on a computer monitor. For extra security, hook and loop fasteners are provided as well as two holes for #4 self-threading screws.

The Control Console is equipped with a 7' line cord, so in must be installed in the vicinity of the Power Supply. The recommended location is near the main controls for the scanner.

3.1.6 INSTALLATION OPTIONS

⚠ WARNING! ⚠

DO NOT place screws in any electrical/medical device.



Item	Description
A	Control Room
B	CT Scanner
1	OptiStat Powerhead
2	10' Coiled Cord
3	Wall Plate
4	75' Extension Cord
5	Power Supply
6	10' Line Cord
8	Remote Console
9	7' Console Cable
11	Wall Hanger Assembly

Figure 3-1-2 Installation Connections

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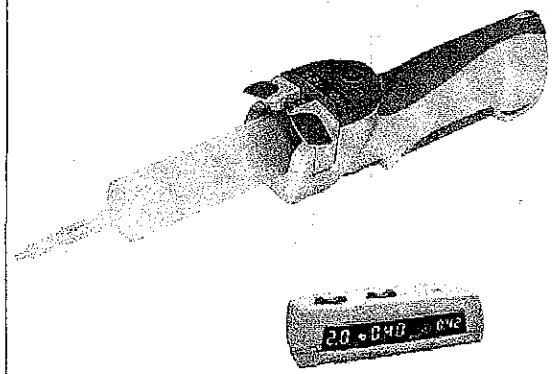
Liebel-Flarsheim

OptiStat™

Contrast Delivery System



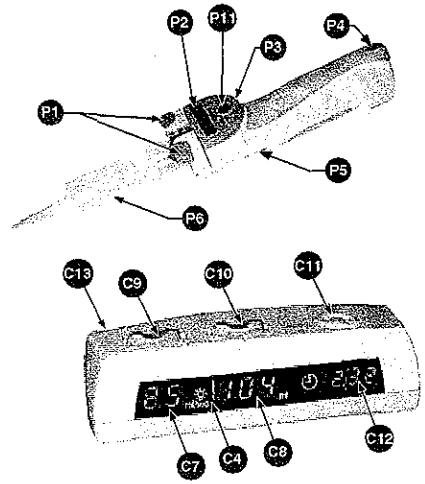
Quick Reference Guide

810813-B

This guide is intended as a quick reference. It is not *complete or detailed in its content.* Read all OptiStat Operator, Service, and Installation documentation before using procedures defined in this guide. Failure to follow this instruction may result in damage to equipment or possible personal injury.

Read the Operators manual for complete instructions.

Keys and I[illegible]ators



Powerhead	Console	Function
P1		Syringe Clamp
P2		Display
P3		Keypad
P4	C4	Status Indicator • Green = Enabled • Multi-color Sweep = Injecting • Red = Error or Fault • Amber = Paused • Off = Inactive
P5		Purge-Retract Trigger
P6		PF = 125mL LF prefilled
		UF = 130mL Mallinckrodt Empty
	C7	Flow Rate Display
	C8	Volume Display
	C9	Increase/Decrease Flow Rate Key
	C10	Increase/Decrease Volume Key
P11	C11	Start/Stop Key
	C12	Scan Delay Timer - Indicates elapsed time from start of injection
	C13	*On/Off Button (on back) controls pow* to Console and Powerhead

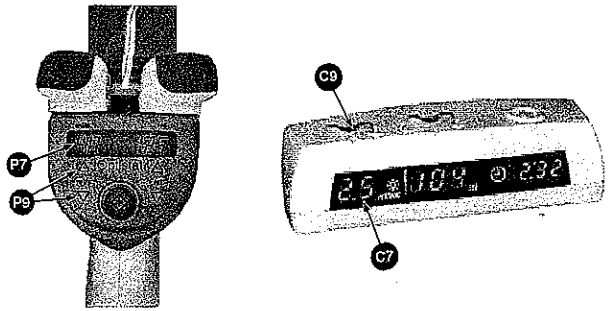
Changing Parameters

Flow Rate and Volume parameters are changed by pressing the increase/decrease keys on the Powerhead or Console.

Flow Rate

Two digit display in milliliters per second (ml/s).

Powerhead	Console	Function
P7	C7	Flow Rate Display
P9	C9	Increase/Decrease Flow Rate Keys

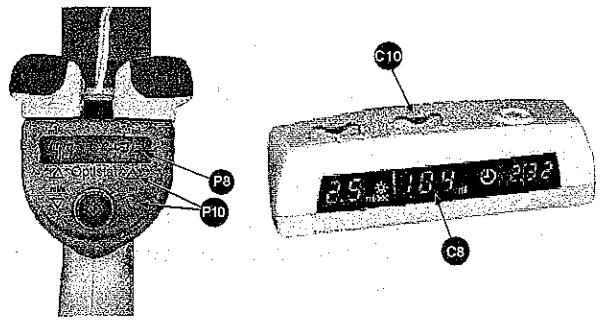


Volume

Three digit display in milliliters (ml).

Note: Always make sure the correct syringe volume is selected.

Powerhead	Console	Function
P8	C8	Volume Display
P10	C10	Increase/Decrease Volume Keys



Common Problems

I turned the injector ON, pressed a key, and a fault occurred!

At power "ON", the injector runs its self diagnostic check. If keys are pressed during this time (15 seconds) a fault will occur. To correct fault, restart injector and wait at least 15 seconds before pressing any keys.

The injector will not enable!

Check syringe size selection "PF " or "UF" . Refer to Syringe Set-up.

Dashes appear in Flow Rate and Volume display (-.--).

Drive Ram is not completely retracted. Fully depress Retract Trigger until ram is fully retracted.

Error Codes

UE 001 - Enable sequence not completed correctly.

Check for air in syringe and restart the enable sequence.

UE 002 - Drive Ram does not move forward with the left syringe clamp in the open position.

UE 003 - Drive Ram is not completely retracted. Fully depress Retract Trigger until ram is fully retracted.

F 175 - Indicates Console is not communicating to the Powerhead.

This condition is normal for a short time during the power-up sequence.

F 060 - The average flow rate was reduced due to abnormally high restriction in the I.V. line.

A pinched extension line, blocked Angiocath or high flow rates with a small Angiocath can cause this error.

The injector will beep, but will continue to run unless the flow rate drops below 50% of the programmed value.

F 061 - This error will pause the injector. The flow rate has drop below 50% of the programmed value.

Check for pinched lines or other potential restrictions. If the problem is resolved, pressing the start button can restart the injector.

For other error codes, check cable connections and restart the OptiStat. If the problem persists, call customer service at (800) 877-0791.

ringe Set-Up

The injector rem...ers the last syringe setting. If you change syringe size, you must change the syringe setting.

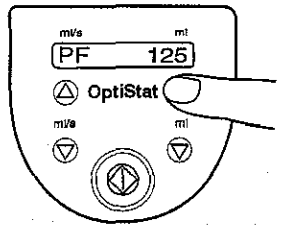
Syringe types are as follows:

PF = Prefilled Ultraject Syringe
Fill volumes are: 125, 100, 75, and 50mL

UF = Empty 130mL Liebel-Flarsheim

To change syringe setting proceed as follows:

1. First identify syringe type.
2. Press and hold the Volume Increment key until the volume display stops incrementing. Continue to hold the Increment key for a few seconds until "PF" or "UF" appears in the Flow Rate Display.



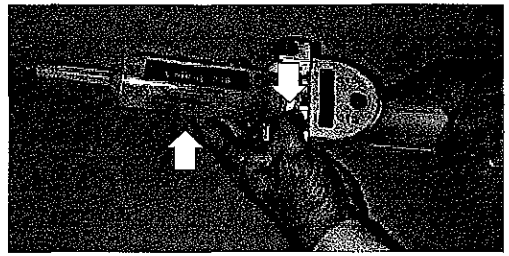
3. Press the Volume Increment or Decrement key to set syringe type and/or fill volume.
4. Press one of the Flow Rate keys, or wait approximately 10 seconds to return to set-up mode.

Enabling an Ultr ct Syringe

Set syringe setup to PF 125mL

To safeguard from inadvertently injecting air, this process is done at the Powerhead.

1. Attach luer-nut and tubing to the syringe.
2. Insert syringe into Powerhead clamps.

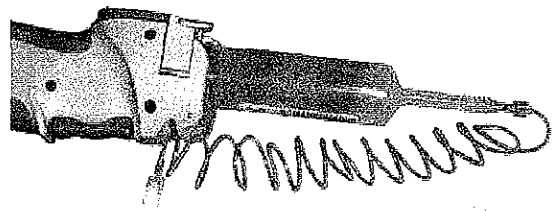


3. Purge air from syringe and tubing by pointing the syringe tip upward, then use the Purge/Retract trigger to purge air.

⚠ WARNING! ⚠

The operator is responsible to ensure that all of the air is completely evacuated from the system.

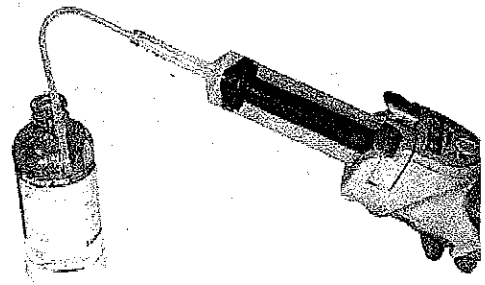
4. The Powerhead status indicator light P4 will illuminat green indicating the unit is enabled and ready to inject
5. Hang Powerhead in holder and attach the tubing in th slot under the syringe clamp.



Enabling a 0mL Empty Syringe

Set syringe setup to or 130.

1. Insert syringe into Powerhead clamps.
2. Fully extend drive ram by holding the Purge/Retract trigger.
3. Attach "J" shaped Handfil straw supplied with syringe.



4. Fill syringe to desired volume.
5. Attach extension tubing to syringe.
6. Purge air from syringe and tubing by pointing the syringe tip upward. Then use the Purge/Retract trigger to purge air.

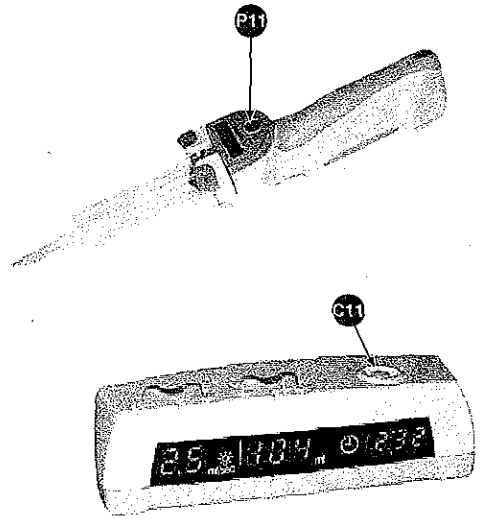
⚠ WARNING! ⚠

The operator is responsible to ensure that all air is completely evacuated from the system.

7. The Powerhead rear indicator light will illuminate green indicating the unit is enabled and ready to inject.
8. Hang Powerhead in holder and attach the tubing in the slot under the syringe clamp.

Starting the In ion

After the injector is successfully programmed, enabled, and attached to the patient's IV access line, pressing P11 or C11 will start the injection.



Pausing the Injection

Pressing any button on either the Console or Powerhead will immediately pause the injection. When paused, the status indicator light on the Console and Powerhead will flash amber. At this time the flow rate and volume settings can be changed. Pressing the start button on the Console or Powerhead will restart the injection.

Elapse Timer

The Elapse timer on the remote Console will start when the injection is started. It will continue to run if the injection is paused.

Disabling the Injection

Retracting the Drive Ram after an injection will: disable the injector, reset the timer, and will not allow the injector to be re-enabled until the proper fill sequence is repeated.